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Patient safety initiatives in obstetrics: A Rapid Review

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Patient safety initiatives in obstetrics: A Rapid Review

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27 ABSTRACT

28 **Objectives:** This review was commissioned by the World Health Organization (WHO), South
29 Africa – Country office because of an exponential increase in medical litigation claims related to
30 patient safety in obstetrical care in the country. A rapid review was conducted to examine the
31 effectiveness of quality improvement (QI) strategies on maternal and newborn patient safety
32 outcomes, risk of litigation, and resulting costs.

33 **Design:** A rapid review of the literature was conducted to provide decision-makers with timely
34 evidence. Medical and legal databases (e.g. MEDLINE, EMBASE, LexisNexis Academic, etc.)
35 and reference lists of relevant studies were searched. Two reviewers independently performed
36 study selection, abstracted data, and appraised risk of bias. Results were summarized narratively.

37 **Interventions:** We included randomised clinical trials (RCTs) of QI strategies targeting health
38 systems (e.g. team changes) and healthcare providers (e.g. clinician education) to improve the
39 safety of women and their newborns. Eligible studies were limited to trials published in English
40 between 2004 and 2015.

41 **Primary and secondary outcome measures:** RCTs reporting on patient safety outcomes (e.g.
42 stillbirths, mortality, and caesarean sections), litigation claims, and associated costs were
43 included.

44 **Results:** The search yielded 4,793 citations, of which 10 RCTs met our eligibility criteria and
45 provided information on over 500,000 participants. The results are presented by QI strategy,
46 which varied from one study to another. Studies including provider education alone (1 RCT),
47 provider education in combination with audit and feedback (2 RCTs) or clinician reminders (1
48 RCT), as well as provider education with patient education and audit and feedback (1 RCT),

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reported some improvements to patient safety outcomes. None of the studies reported on litigation claims or the associated costs.

Conclusions: Our results suggest that some QI strategies may improve the safety of women and their newborns during childbirth.

Keywords: Obstetrics, patient safety, quality improvement, review, knowledge synthesis, medical malpractice

Word Count: Abstract 288 (max 300), main text 4278 (suggested max 4000), 2 figures, 1 table, 2 supplementary files.

Strengths and limitations of this study

- A rapid review was conducted to identify quality improvement (QI) strategies for obstetrical care with supporting evidence from randomised clinical trials (RCTs) published in English between 2004 and 2015; a key limitation of the current review was the streamlined search and inclusion criteria used to accommodate the 6-week timeline for our decision-makers.
- To ensure the relevance of our review, commissioners from the WHO South Africa-Country office were engaged in defining the review scope, developing review questions, approving the protocol and literature search strategies, and identifying key messages.
- A comprehensive search of the medical and legal databases, websites, and reference lists of relevant studies were performed within the review scope.
- Study selection, data abstraction and quality appraisal were performed in duplicate to minimize subjectivity and random errors.

INTRODUCTION

The rising costs in healthcare delivery and safety concerns of patients due to medical errors and liability claims have resulted in the development of policies to promote patient safety in medical practice.¹⁻⁴ An increase in the number of medical litigation cases and related costs is especially apparent in the field of obstetrics.⁵⁻⁷ Clinicians and decision-makers working in obstetrical care recognize the need to ensure the safety of patients, and many professional organizations (e.g. American College of Obstetricians and Gynecologists, National Health Service) have taken steps to make this a priority by evaluating current practices and introducing patient safety initiatives in their organizations.^{3 5 8} Implementation of patient safety initiatives, including quality improvement (QI) strategies, aim to reduce the occurrence of avoidable adverse events and improve the quality of care.^{8 9} QI strategies can target health systems (e.g., team changes, case-management), healthcare providers (e.g., provider education, audit and feedback), and/or patients (e.g. patient education, self-management). These strategies are typically complex interventions with interacting components involving various stakeholders and targeting more than one level of care.^{10 11} The evaluation of the effectiveness of these complex interventions is challenging and as such, the impact of QI interventions on patient safety outcomes remains unclear.

Another rapid scoping review on the effectiveness of medical liability reforms and QI strategies in improving litigation-related outcomes in obstetrics identified several case studies in which the implementation of QI strategies may be associated with a reduction in patient harms and medical liability claims.¹² Since these findings were primarily limited to case studies with small sample sizes, an examination of their effectiveness was not feasible. The current rapid review, therefore, aimed to examine the effectiveness of QI strategies on patient safety outcomes, medical litigation claims, and the associated costs.

93 METHODS

94 Commissioning Agency

95 Due to an exponential increase of litigation claims related to patient safety in obstetrical care in
96 South Africa, the World Health Organization (WHO) South Africa – Country Office
97 commissioned a review of patient safety initiatives. In order to provide decision-makers with
98 timely evidence synthesis, a rapid review approach was collectively agreed upon and employed
99 to be completed within a 6-week timeline. Rapid reviews simplify the systematic review process
100 to produce information in a short period of time for a decision-maker.¹³ The streamlined steps
101 followed in this review included limiting the study design to randomised clinical trials (RCTs),
102 the search dates to a period of 10 years, and the language to English.

103 Protocol

104 A protocol for this review was developed in collaboration with the review commissioner and
105 revised by systematic review methodologists and clinicians (Supplementary File 1; Appendix A).
106 The conduct and reporting of this review followed guidance from the Preferred Reporting Items
107 for Systematic Reviews and Meta-analysis (PRISMA) statement (Supplementary File 2).¹⁴

108 Eligibility criteria

109 The following PICOST eligibility criteria were developed *a priori*:

110 **Population:** Pregnant women and/or newborns receiving care from professional healthcare
111 practitioners (e.g., physician, nurse, midwife) were eligible for inclusion.

112 **Interventions:** Interventions with the goal of promoting or ensuring patient safety in obstetric
113 care (full definitions are provided in Supplementary File 1; Appendix B) were eligible for
114 inclusion. The patient safety interventions (hereafter referred to as QI strategies) targeted health

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3 115 systems (e.g. clinician reminders, team changes) and/or healthcare providers (e.g., provider
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5 116 education, audit and feedback). Studies with interventions that only targeted patients (e.g.,
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7 117 patient education, self-management) or community health workers (e.g., village leaders,
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9 118 volunteers) were excluded because the WHO was interested in interventions that they could
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11 119 implement at the health system or healthcare provider levels.
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14 120 **Comparators:** Other patient safety interventions or usual care were eligible comparators.
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16 121 **Outcomes:** Adverse safety outcomes (e.g., physical or mental damage or injury to the pregnant
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18 122 woman, fetus, or newborn), litigation claims (e.g., lawsuits or other legal action), and the
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20 123 associated costs (e.g., cost of patient safety initiatives to reduce harms and litigation or
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22 124 expenditure due to medical adverse event or legal outcome) were eligible for inclusion. The
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24 125 following outcomes were selected by the clinicians on the team and review commissioner as key
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26 126 safety outcomes of interest: stillbirths, perinatal mortality, neonatal morality, maternal mortality,
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28 127 and caesarean sections. However, other patient safety outcomes (e.g. neonatal morbidity, blood
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30 128 loss, hemorrhage) reported in the included studies were also eligible.
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33 129 **Study Design:** Due to the rapid nature of the review, only RCTs, including cluster-randomised
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35 130 trials, were included. Quasi-randomised trials and non-randomised studies were not eligible for
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37 131 inclusion.
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40 132 **Other:** Additional limits imposed to accommodate the 6-week timeline included publication date
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42 133 (i.e. 2004-2015) and language of publication (i.e. English only).
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48 134 **Information sources and literature search**
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50 135 An electronic search of the literature was conducted in MEDLINE, EMBASE, LexisNexis
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52 136 Academic, LegalTrac and the Legal Scholarship Network on August 13, 2015. The search was
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137 limited to RCTs (using a validated search filter),¹⁵ as well as papers published in English from
138 2004 to 2015.

139 The MEDLINE search strategy was developed by an experienced librarian (Dr. McGowan) in
140 consultation with the research team, approved by the review commissioner, and peer-reviewed
141 by another librarian (Dr. Cogo) using the Peer Review of Electronic Search Strategies (PRESS)
142 checklist.¹⁶ The final search strategy for MEDLINE can be found in Supplementary File 1;
143 Appendix C, and was adapted for the other electronic databases. The bibliographic search was
144 supplemented by searching websites of the WHO (<http://www.who.int/en/>) and Canadian
145 Medical Protective Association (<https://www.cmpa-acpm.ca/en/home>) and scanning reference
146 lists of all included RCTs.

147 **Study selection**

148 The search results were screened using our proprietary web-based tool, Synthesi.SR.¹⁷ The
149 inclusion criteria and screening questionnaire were established *a priori* for screening of titles and
150 abstracts, and full-text articles. To ensure inter-rater agreement, a random sample of 50 citations
151 was pilot-tested among the review team with 100% agreement. The remaining search results
152 were independently screened by pairs of reviewers (JA, WZ, VN, RC, JDI, MG, CW, MK, RW,
153 SM) and discrepancies were resolved by a third reviewer (JA, WZ). The same process was
154 followed for screening of potentially relevant full-text articles in which a pilot-test was
155 conducted on a random sample of 20 full-text articles with 90% agreement across reviewers.

156 **Data abstraction**

157 Data were collected for predefined sets of items using a standardized form in Excel. Data items
158 included study characteristics (e.g., author, country of conduct, study design), patient
159 characteristics (e.g., target population, sample size), description of the QI strategies (e.g.,

provider education, team changes), and patient safety outcome results (e.g., stillbirths, neonatal mortality, litigation cases, costs). The form was pilot-tested on one article with a facilitated team meeting for discussion on the discrepant items. Subsequently, pairs of reviewers performed data abstraction, independently (JA, WZ, VN, RC, JDI, MG). Differences in abstraction were resolved by discussion and/or the involvement of a third team member (JA, WZ, VN, RC). The QI strategies used in each treatment arm were identified and categorized by an experienced systematic review methodologist (ACT) and clinician (SES) independently, and discrepancies were resolved through discussion.

Risk of bias assessment

Risk of bias of the included RCTs was assessed using the 7-item Cochrane Risk-of-Bias tool¹⁸ by pairs of reviewers independently (JA, WZ, VN, RC, JDI, MG). Since all reviewers were experienced with this tool, we did not conduct a pilot-test. For the “other bias” component of the tool, we assessed the potential for funding bias, as well as the presence of an imbalance in baseline numbers, risk of contamination, and confounding bias due to differences in treatment administration as described by the authors of the included studies. Discrepancies were resolved by a third reviewer (JA, WZ).

Synthesis

Study, patient, and intervention characteristics were summarized using descriptive analysis. All patient outcomes were synthesized narratively.

179 RESULTS

180 The literature search resulted in 4,793 citations (Figure 1). After screening for eligibility based
181 on titles and abstracts, 276 potentially relevant full-text articles were identified and screened for
182 inclusion. Ten RCTs¹⁹⁻²⁸ with one companion report²⁹ met the inclusion criteria and were
183 included.

184 Study characteristics

185 Although all RCTs were published from 2004-2015, they were conducted between the years of
186 1982 and 2011 with study durations ranging from 2^{19 24 26} to 21 years²⁷ (Supplementary File 1;
187 Appendix D). Over 500,000 participants were included across the RCTs from North America
188 (n=5),^{21 24 26-28} South America (n=2),^{19 20} Africa (n=2),^{22 23} and Australia (n=1).²⁵ Two RCTs
189 were randomised at the patient level (RCTs),^{25 27} while 8 were cluster-RCTs randomised at the
190 obstetrics unit, hospital, or district level.^{19-24 26 28}

191 Patient characteristics

192 Two RCTs described QI strategies targeting the health system, such as team changes and case
193 management. One of these RCTs focused on QI strategies implemented for the improvement of
194 outcomes in pregnant women alone,²⁵ while the other involved the care of pregnant women and
195 children up to 2 years of age (Supplementary File 1; Appendix D).²⁷ All cluster-RCTs described
196 QI strategies targeting healthcare providers, such as clinicians, nurses, and midwives.^{19-24 26 28}
197 The intervention settings of the RCTs were hospitals (n=8; 80%), and/or communities (n=3;
198 30%).

199 Risk of bias appraisal

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All 10 RCTs were assessed as having a low risk of ascertainment bias since the outcomes were examined using objective measures (e.g., blood loss; Figure 2). Seven RCTs (70%) were assessed as having a low risk of bias for random sequence generation, as well as low risk of attrition bias. About half of the RCTs were considered to be either high or unclear risk of bias for allocation concealment and selective reporting. Three studies were assessed as having a high risk of “other bias”^{21 25 28} due to systemic between-group differences in the distribution of baseline characteristics, potential bias due to uneven implementation of the intervention in different clusters, and/or failing to assess or adjust for other confounders (e.g., baseline risk of adverse pregnancy outcomes).

Patient safety outcomes

All RCTs reported on patient safety outcomes for mothers and their babies. In total, we identified 26 safety outcomes reported in the 10 included studies. None of the 10 RCTs included in the review reported on outcomes related to litigation or associated costs. As each of the intervention components varied significantly, we were unable to combine the results in a meaningful way using meta-analyses. Therefore results are summarized narratively. The findings of each study are presented below by intervention components. As a supplement to our results, detailed descriptions of each of the included interventions (Supplementary File 1; Appendix E), definitions of outcomes (Supplementary File 1; Appendix F), and study-specific conclusions by outcome (Table 1) are also presented.

219 **Table 1. Summary Results of All Patient Safety Outcomes**

QI strategies	PE		PE+AF		PE+CLR	PE+TC	PE+AF+TC	PE+AF+PTE+CQI	PTR+TC+PTE	CM+TC
Study	Althabe, 2004 ¹⁹	Riley, 2011 ²⁸	Chaillet, 2015 ²¹	Dumont, 2013 ²³	Althabe, 2008 ²⁰	Nielsen, 2007 ²⁶	Horbar, 2004 ²⁴	Colbourn, 2013 ²²	Lumley, 2006 ²⁵	Olds, 2014 ²⁷
Sample Size	n = 149,276 women	n = 28,536 deliveries	n = 184,952 women	n = 197,336 patients	n = 5,466 vaginal deliveries	n = 28,536 deliveries	n = 5,466 vaginal deliveries	n = 20,576 deliveries	n = 184,952 women	n = 197,336 patients
Risk of Bias	AC - Low, SB - Unclear	AC - Unclear, SB - Unclear	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - High, SB - Unclear	AC - Low, SB - Unclear	AC - High, SB - Unclear	AC - Low, SB - Unclear
Key Outcomes										
Stillbirths	o	—	—	o	o	—	—	o	—	?
Perinatal Mortality*	o	—	—	—	—	—	—	✓	?	—
Neonatal mortality†	o	—	—	✓	o	—	—	✓	—	—
Maternal mortality	?	—	o	✓	?	—	—	o	—	?
Caesarean section‡	✓	—	✓	o	—	—	—	—	—	—
Other Outcomes										
Major neonatal morbidity	—	—	✓	—	—	—	—	—	—	—
Minor neonatal morbidity	—	—	✓	—	—	—	—	—	—	—
Infant pneumothorax	—	—	—	—	—	—	o	—	—	—
Unplanned admission to NICU	o	—	—	—	—	?	—	—	—	—
Infant/child deaths	—	—	—	—	—	—	o	—	—	?
1-min Apgar score < 3	—	—	—	—	—	—	o	—	—	—
5-min Apgar score < 4	—	—	o	—	o	—	—	—	—	—
5-min Apgar score 4-7	—	—	o	—	—	—	—	—	—	—
Major maternal morbidity	—	—	o	—	—	—	—	—	—	—
Minor maternal morbidity	—	—	o	—	—	—	—	—	—	—
Maternal admission to ICU	o	—	o	—	?	—	—	—	—	—

QI strategies	PE		PE+AF		PE+CLR	PE+TC	PE+AF+TC	PE+AF+PTE+CQI	PTR+TC+PTE	CM+TC
Study	Althabe, 2004 ¹⁹	Riley, 2011 ²⁸	Chaillet, 2015 ²¹	Dumont, 2013 ²³	Althabe, 2008 ²⁰	Nielsen, 2007 ²⁶	Horbar, 2004 ²⁴	Colbourn, 2013 ²²	Lumley, 2006 ²⁵	Olds, 2014 ²⁷
Sample Size	n = 149,276 women	n = 28,536 deliveries	n = 184,952 women	n = 197,336 patients	n = 5,466 vaginal deliveries	n = 28,536 deliveries	n = 5,466 vaginal deliveries	n = 20,576 deliveries	n = 184,952 women	n = 197,336 patients
Risk of Bias	AC - Low, SB - Unclear	AC - Unclear, SB - Unclear	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - High, SB - Unclear	AC - Low, SB - Unclear	AC - High, SB - Unclear	AC - Low, SB - Unclear
Systematic uterine rupture	—	—	o	—	—	—	—	—	—	—
Perineal lacerations	—	—	o	—	o	?	—	—	—	—
Postpartum blood loss (mL)	—	—	—	—	✓	—	—	—	—	—
Postpartum hemorrhage > 500mL	—	—	—	—	✓	—	—	—	—	—
Postpartum hemorrhage > 1000mL	—	—	—	—	✓	—	—	—	—	—
Surfactant use (in delivery room)	—	—	—	—	—	—	✓	—	—	—
Surfactant use (2 hours post-delivery)	—	—	—	—	—	—	✓	—	—	—
Weighted adverse outcome score (WAOS) §	—	✓	—	—	—	o	—	—	—	—
Adverse outcome index (AOI)	—	—	—	—	—	o	—	—	—	—
Severity index	—	—	—	—	—	o	—	—	—	—

AC, allocation concealment; AF, audit and feedback; CLR, clinician reminders; CM, case management; CQI: continuous quality improvement; ICU, intensive care unit; NICU, neonatal intensive care unit; PE, provider education; PTE, patient education; PTR, patient reminders; QI, quality improvements; SB, selection bias; TC, team changes

Footnotes:

- *Colbourn, 2013 found community intervention was significantly protective when compared to no community intervention. All other comparisons in this study showed no significant difference.
- † Dumont, 2013 found safety initiative to be statistically protective only <24hours after birth. Colbourn, 2013 found facility-based + community intervention to be significantly protective when compared to community intervention alone.
- ‡ Refers to non-Emergency C-sections
- § Of the three comparison arms, Riley 2011 only found the combination of didactic and in-situ training to be significantly protective. Didactic alone or in-situ alone showed no significant difference.

✓ = significant ly protective
x = significantly harmful
o = no difference
— = outcome not reported
? = effect not reported

231 *Provider Education (n=2)*

232 Althabe *et al*¹⁹ compared the use of mandatory second opinion by a clinician trained to use a
233 new decision-aid tool to usual care before cesarean section. This decision-aid tool provided
234 clinicians with suggestions and recommendations on how to address the cause of six primary
235 indications for caesarean section. This cluster-RCT of 149,276 pregnant women found a small
236 significant reduction in the rate of caesarean section for the intervention versus usual care
237 (relative rate reduction 7.3%, 95% CI 0.2-14.5). Other safety outcomes of maternal, perinatal and
238 neonatal mortality, as well as unplanned admission to the neonatal intensive care (NICU) and
239 intensive care unit (ICU) showed no significant differences between groups. This RCT had an
240 unclear risk of selective reporting bias and other bias.

241
242 The impact of team and staff training was evaluated in a cluster-RCT published by Riley and
243 colleagues²⁸. Three hospitals in the United States were compared in this RCT: one control
244 hospital (no intervention), one hospital used didactic training only (based on an evidence-based
245 teaching plan with a focus on leadership, situation monitoring, mutual support and
246 communication), and one hospital received the full intervention (didactic training with patient
247 simulations from triage through labor and recovery). The 4-year follow-up showed no
248 statistically significant differences in the pre- and post-intervention results in the hospitals
249 administering the control and didactic programs on the Weighted Adverse Outcome Score
250 (WAOS) including 10 adverse outcomes. However, the hospital receiving the full intervention
251 reported a statistically significant change in WAOS score, suggesting that a complex intervention
252 including didactic training with situational simulation can improve the safety of obstetrical
253 patients. The overall quality of this study is low due to an unclear risk of bias on random

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3 254 sequence generation, incomplete outcome reporting, selective reporting bias, and allocation
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5 255 concealment.
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9 256 *Provider Education with Audit and Feedback (n=2)*
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11 257 A cluster-RCT by Chaillet *et al*²¹ conducted across 32 hospitals in Quebec assessed the effect of
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13 258 a multifaceted strategy to promote professional onsite training, including staff education,
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15 259 educational outreach, and audit and feedback, on the number of caesarean deliveries and other
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17 260 maternal and neonatal outcomes. No intervention was administered to the 16 hospitals in the
18
19 261 control arm. During the 2 year intervention and follow-up period, there were 105,351 deliveries
20
21 262 included. A small, statistically significant reduction in number of caesarean births were observed
22
23 263 in the intervention arm (p=0.04). The intervention group also had statistically significantly lower
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25 264 major neonatal morbidity (p=0.03) and a significantly smaller increase in minor neonatal
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27 265 morbidity (p<0.001) when compared to the control group. There were no significant differences
28
29 266 between groups in maternal morbidity. This RCT had a low risk of bias across all components
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31 267 except allocation concealment (unclear) and other risk of bias (high).
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38 269 Dumont *et al*²³ reported the effects of a complex intervention in a cluster-RCT conducted in
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40 270 Senegal and Mali. First, opinion leaders (physicians and midwives) from 23 hospitals attended
41
42 271 an interactive workshop on evidence-based clinical practice and the clinical audit process. Then,
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44 272 these opinion leaders returned to their respective hospitals to launch maternal death audits and
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46 273 provide on-site training, including quarterly educational outreach visits. The control arm
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48 274 included 95,236 patients in 23 hospitals that did not receive any intervention. Outcomes assessed
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50 275 at baseline and after 4 years of follow-up on a total of 191,157 patients found that maternal death
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52 276 reviews and on-site training may be beneficial for certain populations. Compared to the control
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group, the intervention arm resulted in better maternal mortality rates (odds ratio 0.85, 95% CI 0.73-0.98), although this was limited to capital and district hospitals (where mild complications were managed as the first level of care, prior to the involvement of regional or national level hospitals). This RCT was assessed as having a low risk of bias on all components except random sequence generation and allocation concealment, which were both scored as unclear risk of bias.

Provider Education with Clinician Reminders (n=1)

Althabe *et al*²⁰ published a cluster-RCT exploring a multi-component behavioral intervention to facilitate the implementation of two evidenced-based practices: the selective use of episiotomy and active management of the third stage of labor. The intervention involved the use of opinion leaders, staff training, and staff reminders. Ten hospitals in Argentina and Uruguay reporting 2,114 deliveries acted as the treatment arm. Nine hospitals with 2,185 vaginal deliveries formed the control group and received no intervention besides the standard in-service training. The outcomes of interest were assessed at baseline and at 18 months. When looking specifically at the adverse events to patients, there was a statistically significant relative rate reduction in postpartum hemorrhage and blood loss in the intervention arm for both 500ml or more (45%, 95% CI[confidence interval] 9 to 71) and 1000ml or more (70%, 95% CI 16 to 78). Maternal death, maternal admission to the intensive care unit, neonatal death, stillbirths, or Apgar score<4 did not result in a significant difference. The RCT was assessed as having an unclear risk of bias associated with random sequence generation and allocation concealment.

Provider Education with Team Changes (n=1)

Nielsen and colleagues²⁶ evaluated the effect of staff teamwork training on adverse outcomes in labor and delivery units in the United States. Teamwork training was administered in two parts with selected staff attending training sessions emphasizing communication and team structure,

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3 300 and then returning to their home hospitals to train other staff members. Analysis was conducted
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5 301 on 28,536 deliveries. The Adverse Outcome Index (AOI) was used to calculate the proportion of
6
7 302 patients with one or more adverse outcomes. The WAOS was also used to consider the relative
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9
10 303 severity of the included adverse outcomes. Some of the adverse events considered in these scores
11
12 304 included maternal death, neonatal death, uterine rupture, maternal admission to the ICU,
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14 305 unplanned admission to the NICU, Apgar score <7, and birth trauma. However, no statistically
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16
17 306 significant differences between groups were observed for the AOI, WAOS, or any of the
18
19 307 individual adverse outcomes assessed. The risk of bias for this RCT was deemed low for all
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21
22 308 items except allocation concealment.

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25 309 *Provider Education with Audit and Feedback and Team Changes (n=1)*

26
27 310 The RCT by Horbar *et al*²⁴ evaluated a multi-component patient safety intervention to promote
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29 311 evidence-based surfactant treatment for preterm infants, including individualized audit and
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32 312 feedback cycles, education and training of staff, and collaboration among intervention arm
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34 313 teams. Fifty seven hospitals administered the patient safety intervention, while another 57
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36 314 hospitals acted as the control. The use of surfactant in the delivery room was significantly higher
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39 315 in the intervention group than the control group (adjusted odds ratio 5.38, 95% CI 2.84 to 10.20),
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41 316 while the intervention hospitals had significantly lower surfactant treatment more than 2 hours
42
43 317 after birth when compared to the control hospitals (adjusted odds ratio 0.35, 95% CI 0.24 to
44
45 318 0.53). The other outcomes, including pneumothorax and infant mortality, were not found to be
46
47
48 319 significantly different. The RCT had a high risk of bias with respect to allocation concealment
49
50 320 and an unclear risk of selective outcome reporting bias.

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53 321 *Provider Education with Audit and Feedback, Patient Education and Continuous Quality*
54
55 322 *Improvement (n=1)*

323 In rural Malawi, Colbourn *et al*²² conducted a two-by-two factorial cluster-RCT examining the
324 use of a women's group community intervention and a facility-based quality improvement
325 intervention to reduce maternal, perinatal and neonatal mortality. The first group received the
326 community intervention consisting of patient education, the second group received facility-based
327 provider education and audit and feedback, the third group received both community and
328 facility-based interventions and the final group acted as a control arm. The analysis consisted of
329 4912 infant births in the control group, 5335 in the facility group, 5080 in the community group
330 and 5249 in the combined group. The neonatal mortality rate was 22% lower in the facility-based
331 + community interventions combined compared to control (adjusted odds ratio 0.78, 95% CI
332 0.60 to 1.01). On the other hand, the community intervention group alone had a significantly
333 lower perinatal mortality rate (16% lower) when compared to control (adjusted odds ratio 0.84,
334 95% CI 0.72 to 0.97). No significant effects were reported for maternal mortality. The RCT was
335 assessed as having a low risk of bias on all items except selective outcome reporting, which was
336 unclear.

337 *Patient Reminders with Team Changes and Patient Education (n=1)*

338 Lumley *et al*²⁵ conducted a RCT in Australia to assess the impact of a pre-pregnancy
339 advice/counseling service offered to new mothers (initiated by two obstetricians) on the well-
340 being of their second-born children. There were 392 women in the intervention arm who were
341 identified after the birth of their first child. These women worked with a midwife (i.e. team
342 changes) to identify current health and lifestyle problems, assess family/genetic history, receive
343 education and referrals as needed, and discuss and develop an appropriate plan for their next
344 pregnancy (including a reminder card). Meanwhile 394 women in the control arm received a
345 home visit with an opportunity to discuss their first pregnancy and ask questions. Outcomes were

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3 346 assessed after the birth of the second child. Infants born to mothers who received counseling
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5 347 were more likely to be of lower birth weight than those who did not, and there were no
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8 348 significant differences between the groups in secondary outcomes such as perinatal deaths and
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10 349 congenital malformations. The RCT had an unclear risk of selective reporting bias, and high risk
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12 350 of bias on both the allocation concealment and incomplete outcome data items.
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16 351 *Case Management and Team Changes (n=1)*
17

18 352 A RCT was conducted to determine the effect of prenatal and infant home visits by nurses on
19
20 353 maternal and child mortality by Olds *et al*²⁷. Participants, mostly African-American women
21
22 354 residing in very poor neighborhoods, were randomised to one of four treatment arms during
23
24 355 pregnancy and were followed for 2 years. In treatment 1, 166 women received free transportation
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26 356 for prenatal appointments. In addition to transport, 514 women in treatment 2 also received some
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28 357 developmental screening and referral services. The third treatment arm including 230 women
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30 358 added nurse home visits during pregnancy as well as 2 postpartum home visits, while 228
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32 359 women in treatment 4 received the most comprehensive intervention with transport, screenings,
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34 360 nurse home visits during pregnancy and until the child was 2 years old. Maternal and infant
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36 361 mortality outcomes were collected for all treatment arms after two years of follow-up.
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39 362 Participants in the combined control arm (treatment 1 + treatment 2) had more natural,
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41 363 preventable, and total infant deaths when compared women receiving treatment 3 and 4
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43 364 combined. Survival curves were created for each of the treatment arms. When projecting to 21
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45 365 years after randomisation, all-cause mortality in mothers was statistically significantly higher in
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47 366 treatment 1 + treatment 2 when compared to treatment 3 alone (p=0.007) or when compared to
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49 367 treatment 3 + treatment 4 combined (P=0.008). The RCT was assessed as having unclear
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51 368 allocation concealment, incomplete outcome data and selective reporting bias.
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DISCUSSION

We conducted a rapid review and identified 10 RCTs written in English and published within 10 years on complex interventions that can be used to improve patient safety in obstetrics. The included RCTs examined a broad range of complex patient safety interventions in obstetrics with some treatment arms including only one QI strategy, while others were multi-faceted interventions including up to four QI strategies. Many of the included studies had a provider education component and the results suggest that this intervention may improve outcomes for some settings. Results from two RCTs indicated that provider education with audit and feedback may improve patient safety, specifically by lowering neonatal morbidity and caesarean births,²¹ as well as neonatal and maternal mortality,²³ when compared to usual care. In another RCT, patient's receiving provider education combined with clinician reminders had reduced postpartum blood loss and hemorrhage when compared to control groups in similar settings.²⁰ Finally, an RCT comparing the use of provider education with patient education and audit and feedback compared to community intervention alone, demonstrated an improvement in patient safety through a reduction in neonatal mortality.²² A future systematic review, however, should be conducted on this topic to provide a definitive conclusion on whether these interventions are indeed effective. In addition, a cost-effectiveness analysis could be conducted to determine the cost-effectiveness of these patient safety interventions. Such a systematic review can include a meta-analysis of the QI strategies versus usual care, which will allow the quantification of the effectiveness of these interventions.

The quality of the included RCTs was generally high, with a few areas of concern. It was unclear whether randomisation sequence was sufficiently concealed, or whether selective outcome

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reporting was present, since these items were unclear for half of the included studies. Also, 6 out of 10 RCTs were graded as either ‘unclear’ or ‘high risk of bias’ for the “other bias” category, as differences in baseline characteristics or confounding effects due to differences in treatment administration across providers, departments, or hospitals were concerns reported by the study authors themselves.

A major strength of our review was the timely provision of high-quality evidence for decision-makers. Our rapid review methodology included a comprehensive search of the literature using multiple databases, and study selection, data abstraction and risk of bias assessment performed in duplicate by pairs of reviewers. However, as with any rapid review, there are also some limitations to be considered. In order to conduct this review within a 6-week time frame, we limited results to RCTs published in English within a 10 year time frame. In addition, the literature search was conducted in August 2015 for the purpose of submitting a report to the review commissioners who did not request that we update our findings. Moreover, variation in administration and implementation of the QI strategies across settings is unavoidable, especially in cluster-RCTs, where each hospital acts as an independent unit. Consideration should be made of possible confounding effects as a result of the hospital setting and care practices (e.g. duration, frequency, and provider). Given the number and range of patient safety initiatives included in each study, it is difficult to ascertain how each of the components included in the multi-faceted, complex interventions directly contributed to the observed effects. Additionally, it was challenging to compare across studies as the QI strategies were used to address different clinical questions in each (e.g. prenatal home visits by midwives to reduce preterm births compared to teamwork training in hospitals to promote guideline implementation).The differences in these

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3 415 complex interventions meant we were unable to conduct meta-analysis. Moreover, classifying
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5 416 complex interventions, such as QI strategies, is challenging³⁰ and required two individuals with
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7 417 complementary expertise to conduct this task.
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12 419 Finally, we did not identify any studies specifically addressing litigation claims or undue costs to
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14 420 the healthcare system. However, evidence from case studies suggests that there may be a
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16 421 relationship between a reduction in adverse safety outcomes and a reduction in litigation and
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18 422 losses due to medical errors and malpractice. These reports^{5 31} have found that the introduction of
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20 423 patient safety programs, involving a combination of strategies targeting health systems and
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22 424 healthcare providers, have resulted in the reduction of not only obstetrical adverse events, but
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24 425 also the number of litigation claims and resulting costs. As such, further research is needed to
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26 426 examine the effectiveness of patient safety interventions on these outcomes.
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CONCLUSIONS

Our results suggest that provider education and other QI strategy combinations targeting healthcare providers may improve the safety of women and their newborns during childbirth. In addition, improved patient safety may influence the risk of medical litigation claims and associated costs, however no direct evidence was found for these outcomes. A future systematic review, including a meta-analysis, may be able to provide more definitive conclusions.

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433 **List of Abbreviations**

434 AC: allocation concealment; AF: audit and feedback; AOI: adverse outcome index; CI:
435 confidence interval; CLR: clinician reminders; CM: case management; C-section: cesarean
436 section; CQI: continuous quality improvement; ICU: intensive care unit; NICU: neonatal
437 intensive care unit; PE: provider education; PRESS: peer review of electronic search strategies;
438 PRISMA: preferred reporting items for systematic reviews and meta-analyses; PTE: patient
439 education; QI: quality improvement; RCTs: randomised clinical trials; TC: team changes;
440 WAOS: weighted adverse outcome score; WHO: World Health Organization

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The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Author’s Contribution

JA coordinated the review, screened citations and full-text articles, abstracted data, appraised risk of bias, cleaned the data, interpreted the results, and wrote the manuscript. WZ coordinated the review, screened citations and full-text articles, abstracted data, appraised risk of bias, cleaned the data, and edited the manuscript. BP helped conceptualize the research, interpreted the results, and edited the manuscript. VN, RC, JDI, and MG screened citations and full-text articles, abstracted data, appraised risk of bias, and edited the manuscript. SLB helped conceive the study and edited the manuscript. SES conceived the study, designed the study, obtained the funding, interpreted the results, and edited the manuscript. ACT conceived the study, designed the study, obtained the funding, interpreted the results, and wrote some of the manuscript. All authors approved the final version to be published.

Competing interests

All authors declare that they have no competing interests.

Figures

Figure 1. Study Flow Diagram. Breakdown of the number of studies identified in the literature, assessed for eligibility, and finally included in the rapid review on patient safety initiatives in obstetrics.

Figure 2. Risk of Bias. Aggregate Cochrane Risk-of-Bias appraisal results

For peer review only

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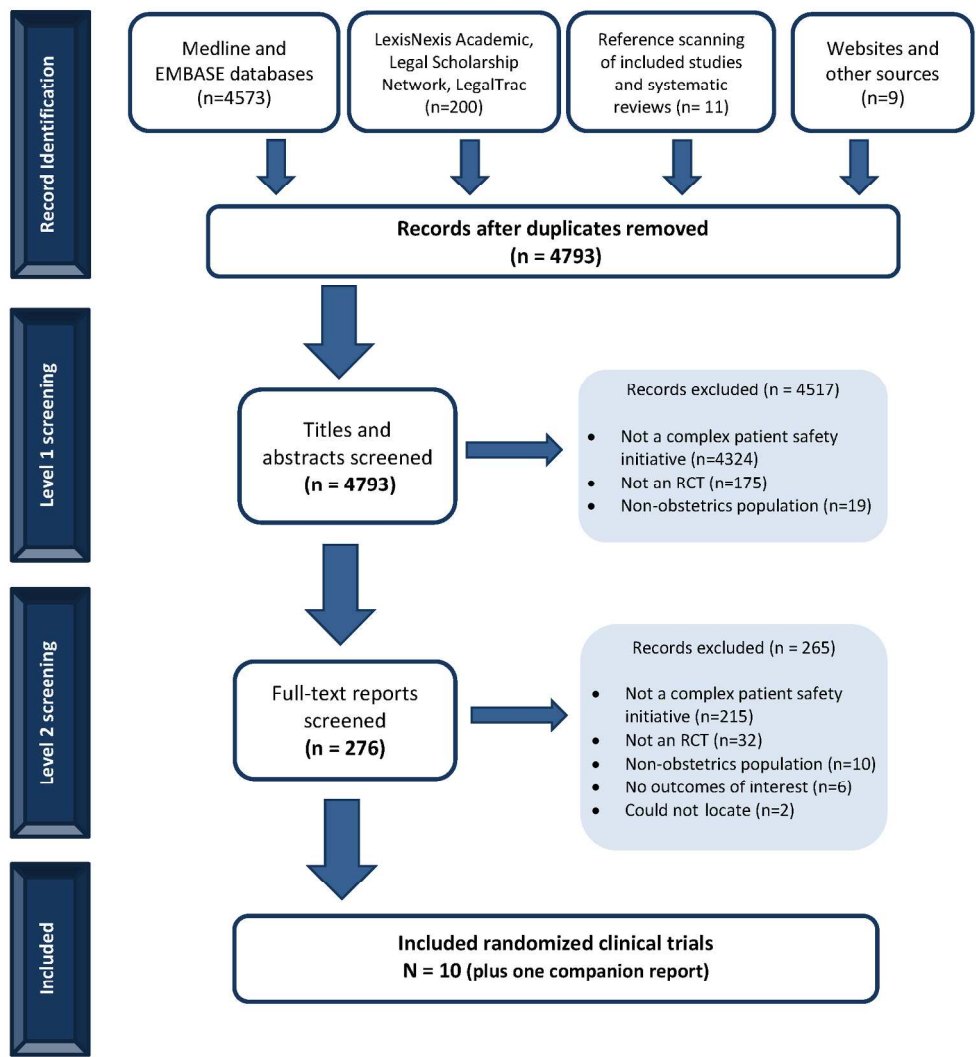
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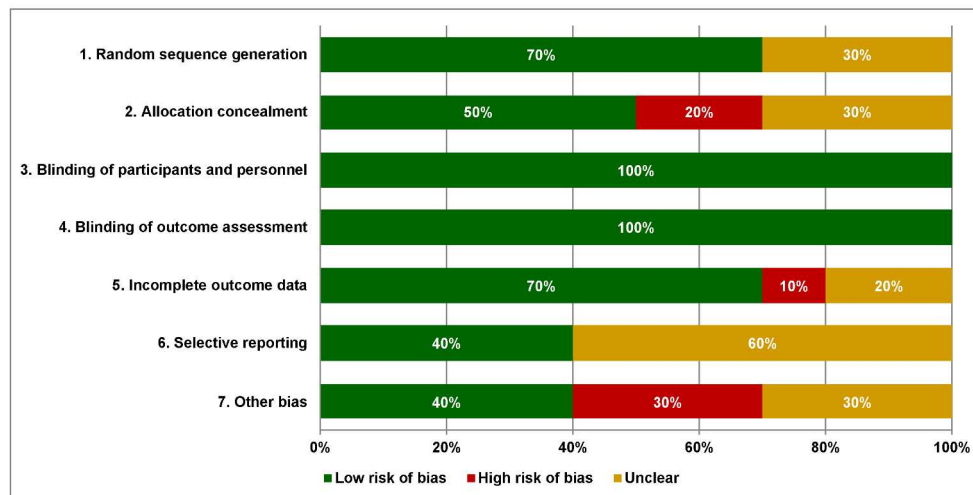
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Study Flow Diagram. Breakdown of the number of studies identified in the literature, assessed for eligibility, and finally included in the rapid review on patient safety initiatives in obstetrics.

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Risk of Bias. Aggregate Cochrane Risk-of-Bias appraisal results

238x121mm (300 x 300 DPI)

Patient safety initiatives in obstetrics: A Rapid Review
Appendices

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Appendix A – Protocol

METHODS:

To answer the research question “What are the available randomized clinical trials that evaluate patient safety interventions in obstetrical care?” we propose doing a rapid scoping review. Below is our proposed method for this rapid scoping review.

Scoping reviews

A scoping review aims to “map the literature on a particular topic or research area and provide an opportunity to identify key concepts, gaps in the research; and types and sources of evidence to inform practice, policymaking, and research”.¹ A scoping review essentially follows the same steps of a systematic review recommended by the Cochrane Collaboration,² except the quality of included studies is not appraised because the purpose is to map out the literature and identify areas to conduct future systematic reviews.

Rapid reviews

Rapid reviews are a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner.³ Depending on the scope and timelines, rapid reviews will streamline some of the processes recommended by the Cochrane Collaboration, such as only 1 reviewer screening the literature search results, abstracting data, and appraising quality. A meta-analysis generally is not conducted for a rapid review.

We have conducted rapid scoping reviews for the World Health Organization (in 2011) and Toronto-Central-Local Health Integrated Network (in 2012) and the lead scientist (Dr. Tricco) on this proposal is interested in studying and improving scoping review and rapid review methods.

Search Strategy

We will use the methodologically rigorous rapid scoping review approach. We will conduct a systematic search across the following electronic databases from inception onwards: MEDLINE (OVID interface), EMBASE (OVID interface), LexisNexis Academic, and the Legal Scholarship Network. The general search terms included those related to obstetrics and patient safety interventions. In order to limit the search, we focused on randomized clinical trials and publications in English from 2004 onwards.

A search conducted on August 13, 2015 of MEDLINE and EMBASE using the defined terms retrieved approximately 5000 citations. We aim to also search to legal databases after we further refine the search strategy with input from the investigators and in consultation with our experienced information specialist. The search strategy has already been peer reviewed by another librarian using the Peer Review of Electronic Search Strategies (PRESS) checklist (see PubMed ID: 19230612). After this exercise, the search strategy was finalized. The information

specialist will execute all final searches, export the results into EndNote, and remove all duplicates from the search results. The results will then be uploaded to Synthesi.SR (<http://knowledgetranslation.ca/sysrev/login.php>), proprietary software available through the Li Ka Shing Knowledge Institute of St. Michael's Hospital.

The following PICOS informed the search strategy:

- Patients:* all obstetrics patients
- Interventions:* patient safety initiatives
- Comparators:* compared to each other or no initiative
- Outcomes:* litigation (number of cases), costs, patient harm (specifically cerebral palsy, shoulder dystocia, non-reassuring fetal status, birth-related neurological injuries)
- Studies:* randomized clinical trials

Study Selection: Screening

Prior to commencing the screening process, a calibration exercise will be conducted to ensure reliability in correctly selecting articles for inclusion. This will entail screening a random sample of 5% of the included citations by all team members, independently. Eligibility criteria will be modified if low agreement is observed between the reviewers (e.g., percent agreement <90%). Two reviewers will then independently screen the remainder of the search results for inclusion using a pre-defined relevance criteria form for all levels of screening (e.g., title and abstract, full-text review). Discrepancies will be resolved by discussion or the involvement of a third reviewer.

Data Abstraction:

A data abstraction form will be drafted and pilot-tested by all team members independently on a random sample of 10 articles and revised iteratively by the study team while the search is completed. It is anticipated that the data items will include information related to the outcomes of interest. Pairs of team members will independently read each article and extract the relevant data. Differences in abstraction will be resolved by discussion or the involvement of a third reviewer.

Synthesis

We will narratively describe the included randomized clinical trials. If possible, a meta-analysis will be considered after the preliminary report has been submitted to Dr. Sarah Barber and her team of the World Health Organization. We will present the outcome results in tables and categorized by intervention, obstetrical issue, and country of origin.

Appendix B – Quality Improvement (QI) Strategies; Full Definitions

Complex Intervention

Complex interventions are important to resolve the common, complex challenges in health care. Quality improvement strategies are considered complex interventions. Complex interventions require detailed descriptions of the intervention to enable researchers to replicate the study, synthesize the results, and implement findings. However, details of complex interventions are often underreported in research. A falls prevention program for seniors is an example of a complex intervention because it often has more than one interacting component administered within the intervention group. For example, the intervention group may receive exercise training with a physiotherapist (exercise training), the physiotherapist may receive training to administer the program specifically to elderly patients (clinician education), and the patients may receive education about falling (patient education). These interventions are challenging to deliver or receive, target more than one level of organization (e.g., both the patient and healthcare provider levels), include multiple dosages and formulations, and allow for the tailoring of interventions across settings (e.g., physiotherapist uses slightly different approaches for different patients in the intervention group).

QI strategies targeting health systems

Case management	Any system for coordinating diagnosis, treatment, or routine management of patients (e.g., arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician. If the study called the intervention “case management” we classified it as such.	Includes nurse phoning regularly to check on patient, nurse calling to promote diet adherence, discharge planning, post-hospital services and home visits
Team changes	Changes to the structure or organisation of the primary health-care team (adding team member, multidisciplinary teams, expansion or revision of professional roles)	Includes multidisciplinary collaboration, appointments with specialists, attending a obstetrics clinic, referrals to specialists or other healthcare providers
Electronic patient registry	General electronic medical record system or electronic tracking. Do not include websites unless patients were tracked over time. To qualify, it had to be a part of the clinical trial as an intervention (i.e., not pre-existing infrastructure unless used more actively)	
Facilitated relay of info to clinicians	Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record (excluding conventional means of	

	correspondence between clinicians.)	
Continuous QI	Interventions explicitly identified as involving the techniques of continuous QI, total quality management, or plan-do-study-act, or any iterative process for assessing quality problems, developing solutions to those problems, testing their effects, and then reassessing the need for further action	
QI strategies targeting health-care providers		
Audit & feedback	Summary of clinical performance of health care delivered by an individual clinician or clinic over a specified period, which was then transmitted back to the clinician. This strategy was strictly based on clinical data and excluded clinical skills. It could include the number of patients with missing tests and dropouts.	
Provider education	Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target disorder or population of patients. Includes conferences or workshops, distribution of educational materials (written, video, or other), and educational outreach visits.	Includes staff training, education workshops, seminars, and outreach
Clinician reminders	Paper-based or electronic systems intended to prompt a health professional to recall patient-specific information (e.g., most recent HbA1c value) or to do a specific task (e.g., foot examination).	
Financial incentives	Interventions with positive or negative financial incentives directed at providers (eg, linked to adherence to some process of care or achievement of some target outcome). This strategy also includes positive or negative financial incentives directed at patients or system-wide changes in reimbursement	Includes gym memberships, drug assistance programs, free medications, Rides to the intervention or parking is not included
QI strategies targeting patients		
Promotion of self-management	Provision of equipment or access to resources to promote self-management. If the study called the intervention promotion of self-management, personalised goal-setting, or action-planning, we included it	Includes problem-solving skills, tracking the number of steps (fit bit), self-help groups

	here. We generally thought this a more active strategy than education of patients)	
Patient Reminders	Any effort (e.g., postcards or telephone calls) to remind patients about upcoming appointments or important aspects of self-care. If the intervention included case management, reminders to patients needed to be explicit.	Includes reminder cards, emails, telephone calls
Patient education - written materials, videos, lectures, other	Patient education related to health	Includes pamphlets, booklets/sheets, brochures on safety initiatives, as well as videos, classes, lectures, workshops, other - "instructions" (unspecified) to promote safety
Motivational interviewing	Motivational interviewing ("a directive and client-centered counselling style that relies upon identifying and mobilizing the client's intrinsic values and goals to stimulate behaviour change, thus encouraging client and family involvement in all aspects of care.")	Motivational interviewing

Appendix C – Medline Search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

- 1 Obstetrics/
2 "Obstetrics and Gynecology Department, Hospital"/
3 exp Obstetric Surgical Procedures/
4 obstetric\$.tw,hw.
5 exp Obstetric Labor Complications/
6 exp "Dilatation and Curettage"/
7 exp Hysterectomy/
8 Sterilization, Tubal/
9 Salpingostomy/
10 exp Pregnancy Complications/
11 cerebral palsy/
12 Asphyxia Neonatorum/
13 (abortion\$ or cervical cerclage or colpotomy or culdoscop\$ or fetoscop\$ or hysteroscop\$ or
14 hysterotomy).tw.
15 (paracervical block\$ or obstetric\$ anesthe\$ or obstetric\$ anaesthe\$).tw.
16 (Cesarean or Episiotom\$ or obstetric\$ extraction\$ or fetal version).tw.
17 ((induc\$ or augmentation or premature or pre-term or preterm or obstructed) adj (labour or
18 labor)).tw.
19 (Abruptio Placentae or breech or Cephalopelvic Disproportion or premature rupture of fetal
20 membrane\$ or prom or fetal membranes premature rupture or Dystocia or Uterine Inertia or
21 Chorioamnionitis or Placenta Accreta or Placenta Previa or Postpartum Hemorrhage or Uterine
22 Inversion or Uterine Rupture or Vasa Previa).tw.
23 (Fetal Death or Fetal Resorption or Stillbirth or perinatal death or peri-natal death or
24 Maternal Death or Birth Injuri\$ or obstetric\$ paralys\$).tw.
25 (pre-eclampsia or dilatation or Curettage or Vacuum aspiration).tw.
26 (asphyxia neonatorum or cerebral palsy or birth asphyxia or fetal pulmonary embolism or
27 dystocia or ((birth adj (trauma\$ or complication\$)) or preeclampsia) or ((birth adj (trauma\$ or
28 complication\$)) or preeclampsia)).tw.
29 exp Dystocia/ or exp Pregnancy Complications, Cardiovascular/
30 or/1-21
31 (safe\$.ti,ab. or exp Safety/ or Err\$.ti,ab. or Adverse.ti,ab.) and (exp Risk Management/ or
32 exp Quality of Health Care/ or exp Medical Errors/ or Safety Management/ or Medical Audit/)
33 patient safety/
34 (patient safe\$ or obstetric\$ safe\$).tw.
35 22 and (23 or 24 or 25)
36 case [reports.pt](#).
37 Observational [Study.pt](#).
38 (News or Newspaper Article or comment or editorial).pt.
39 or/27-29

1
2
3 31 randomized controlled [trial.pt](#).
4 32 (randomized or placebo).mp.
5 33 clinical [trial.pt](#).
6 34 or/31-33
7 35 comparative [study.pt](#).
8 36 26 and 34
9 37 limit 36 to english
10 38 limit 37 to yr=2004-2015
11 39 38 not 30
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Appendix D – Patient and Intervention Characteristics

First Author, Year	Study Design	Study Period	Intervention Provider	Abbreviated Intervention Name	QI Strategy	Intervention Setting	Intervention Setting Description	Sample Size	Duration/ Frequency of intervention
Althabe, 2004 ⁴	cluster RCT	Oct 1998 - Jun 2000	physicians	Decision aid tool training and mandatory second opinion (educational seminar offered to all prior to randomisation)	Provider education	Hospital	18 hospitals (9 in Argentina, 4 in Brazil, 2 in Cuba, 1 in Guatemala, 2 in Mexico)	70,410 pregnant women who underwent delivery	6 months pre-intervention; 7 month intervention
				Control (educational seminar offered to all prior to randomisation)	Provider education	Hospital	18 hospitals (9 in Argentina, 4 in Brazil, 2 in Cuba, 1 in Guatemala, 2 in Mexico)	78,866 pregnant women who underwent delivery	6 months pre-intervention; 7 month intervention
Riley, 2011 ⁵	cluster RCT	2005 - 2008	labour and delivery staff	Didactic training with in-situ patient simulations	Provider education	Hospital	small-sized community hospitals (50 beds); rural/suburban in the US	36 medical personnel; 380 births/year	4 months (30 min webinar, 11 in-situ simulations (30-40mins), 2-hour debriefing immediately following each)
				Didactic training only	Provider education	Hospital	small-sized community hospitals (66 beds); rural/suburban in the US	60 medical personnel; 889 births/year	4 months (30min webinar)

				Control (usual care)	usual care	Hospital	small-sized community hospitals (55 beds); rural/suburban in the US	38 staff; 500 births/year	4 months
Chaillet, 2015 ⁶	cluster RCT	Apr 2008 - Oct 2011	physicians and nurses	Multifaceted strategy (i.e. QUARISMA program) to promote professional onsite training	Provider education; Audit and feedback	Hospital	16 public hospitals in Quebec, Canada	84,227 pregnant women who underwent delivery	3.5 years (1 year pre-intervention, 1.5 intervention, 1 year post-intervention)
				Control (usual care)	usual care	Hospital	16 public hospitals in Quebec, Canada	100,725 pregnant women who underwent delivery	3.5 years (1 year pre-intervention, 1.5 intervention, 1 year post-intervention)
Dumont, 2013 ⁷ [CR: Zongo, 2015 ⁸]	cluster RCT	Sept 2007 - Oct 2011	obstetric teams	Multifaceted intervention (i.e. ALARM course) to promote maternity death reviews and onsite training	Provider education; Audit and feedback	Hospital	23 public first-level and second-level referral hospitals in Senegal and Mali	95,931 pregnant women who underwent delivery	1 year pre-interventions; 2 year intervention (initial 6-day training workshop for healthcare professionals and quarterly educational clinically oriented and evidence-based outreach visits); 1 year post-intervention

				Control (usual care)	usual care	Hospital	23 public first-level and second-level referral hospitals in Senegal and Mali	95,236 pregnant women who underwent delivery	1 year pre-interventions; 2 year intervention; 1 year post-intervention
Althabe, 2008 ⁹	cluster RCT	Sept 2003 - Dec 2006	birth attendants	Multifaceted behavioral intervention	Provider education; Clinician reminders	Hospital	public maternity hospitals (9 in Argentina and 1 in Uruguay)	post-intervention: 2,587 vaginal deliveries; 295 birth attendants 12 month post-intervention: 2,114 vaginal deliveries	intervention: 18 months; post-intervention follow-up: 12 months
				Control (standard in-service training)	Provider education	Hospital	public maternity hospitals (8 in Argentina, 1 in Uruguay)	post-intervention: 2,366 vaginal deliveries; 237 birth attendants 12 month post-intervention: 2,185 vaginal deliveries	intervention: 18 months; post-intervention follow-up: 12 months
Nielsen, 2007 ¹⁰	cluster RCT	Dec 2002 - Mar 2004	clinical staff	Teamwork training (i.e. MedTeams)	Provider education; Team change	Hospital	7 US hospitals (3 military and 4 civilian)	14,200 total deliveries; 1,307 trained personnel	2 month pre-intervention; 3-day training; 5 month post-intervention

				Control (usual care)	usual care	Hospital	8 US hospitals (3 military and 5 civilian)	14,336 total deliveries	2 month pre-intervention; 5 month post-intervention
Horbar, 2004 ¹¹	cluster RCT	May 1999 - Dec 2001	hospital staff	Multifaceted collaborative intervention to promote evidence-based surfactant treatment	Audit and feedback; provider education; team change	Hospital	57 neonatal intensive care units in hospitals in the Vermont Oxford Network, US	3,313 newborns	1 year (one time individualized feedback; 2-day workshop; routine reports)
				Control (usual care with centre-specific routine reports)	Audit and feedback	Hospital	57 neonatal intensive care units in hospitals in the Vermont Oxford Network, US	2,726 newborns	1 year (routine reports)
Colbourn, 2013 ¹²	cluster RCT	Jun 2007 - Dec 2010	volunteer facilitators, village women's groups, health centre facility staff	Community mobilization intervention and facility-based QI intervention	Provider education; audit and feedback; patient education; continuous qi	Community and Hospital	14 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,249 births	16 months pre-intervention; 27 months intervention
			health centre facility staff	Facility-based QI intervention only	Provider education; audit and feedback; continuous qi	Hospital	15 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,335 births	16 months pre-intervention; 27 months intervention

			volunteer facilitators, village women's groups	Community mobilization intervention only	patient education	Community	15 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,080 births	16 months pre-intervention; 27 months intervention
			NA	Control	usual care	Hospital	17 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	4,912 births	16 months pre-intervention; 27 months intervention
Lumley, 2006 ¹³	RCT	May 1982 - Dec 1994	midwives	Pre-pregnancy health intervention	Team change; patient education; patient reminders	Community	Maternal and Child Health (MCH) centres, Australia	392 pregnant women who underwent delivery	one home visit for general pregnancy discussion and as needed during pregnancy
				Control (usual care)	usual care	Community	Maternal and Child Health (MCH) centres, Australia	394 pregnant women who underwent delivery	one home visit for general pregnancy discussion
Olds, 2014 ¹⁴	RCT	Jun 1990 - Dec 2011	community nurse	Transportation only	usual care	Community	public system of obstetric and pediatric care in Memphis, Tennessee,	166 pregnant women who underwent delivery	as needed during pregnancy

					US	
			Transportation with screening and referral services	usual care	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US
						514 pregnant women who underwent delivery
						as needed during pregnancy and once post-partum
			Transportation and home visits	case management; team change	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US
						230 pregnant women who underwent delivery
						as needed during pregnancy and two visits post-partum
			Transportation with screening and referral services, plus home visits	case management; team change	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US
						228 pregnant women who underwent delivery
						as needed during pregnancy and until child 2 years of age
			NA, not applicable; QI, quality improvement; RCT, randomized clinical trials; US, United States			

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Appendix E – Intervention descriptions

First Author, Year	Intervention Description	Abbreviated Intervention Name	QI Strategy
Althabe, 2004 ⁴	Seminar, Guidelines and Mandatory second opinion: The intervention consisted of the implementation of a policy of mandatory second opinion at the hospitals assigned to the intervention group. Second opinion was to be sought by the attending physician systematically before caesarean section. The physician providing the second opinion had to be a person with clinical qualifications equal to or higher than those of the attending physician, working at the same hospital, selected by the obstetrics department for this trial, and who had agreed to follow the clinical guidelines. A physician could have the role of attending physician on some days and consultant on others. To assess the clinical case, the consultant followed guidelines prepared as decision flowcharts, for six primary indications for caesarean section. Each guideline had suggestions about how to deal with the problem that originated the indication. Both physicians discussed the case in relation to the guidelines. After this process, the attending physician made the final decision. The guidelines were made available for all physicians at intervention hospitals. NOTE: All decisions to undertake caesarean sections (either elective or intrapartum) in intervention hospitals were eligible for a mandatory second opinion, except if the woman specifically refused to be seen by a second doctor or the situation was an extreme emergency such as maternal haemorrhage, cord prolapse, suspected uterine rupture, or any situation where the attending physician judged that a delay would constitute malpractice.	Decision aid tool training and mandatory second opinion (educational seminar offered to all prior to randomisation)	provider education
	Control (seminar only): a formal seminar on pregnancy and delivery care offered to all clinicians prior to randomisation	Control (educational seminar offered to all prior to randomisation)	provider education
Riley, 2011 ⁵	Didactic with in-situ simulation: <i>Didactic Training:</i> Didactic training was based on the Team-STEPPS training curriculum, with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in	Didactic training with in-situ patient simulations	provider education

	<p>safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop communication, and shared mental model. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviors from the didactic training.</p> <p><i>In-Situ Simulation:</i> The in-situ simulation for perinatal critical events consisted of five components: (a) briefing, (b) in-situ simulation, (c) debriefing, (d) rapid-cycle follow-through with process improvements, and (e) repetition to reinforce skills and create resiliency. During the briefing, participants who were directly involved in the simulation were educated about the simulation scenarios. The simulated patient was followed from triage, through labor and the operating room (OR), and then to the recovery area. The simulation, which typically ran 30 to 45 minutes, was initiated in a manner similar to a typical handoff, with a brief history from one provider to the next. A two-hour debriefing session, with the use of advanced debriefing techniques, was held immediately following each simulation. Scenarios and triggers were taken from actual occurrences in the hospital unit. We used an event-set methodology to develop scenarios for uterine rupture, placental abruption, and post-partum hemorrhage. The event sets specified phases for each of the three scenarios. Five clinical triggers were designed to prompt NTS behaviors: situational awareness, shared mental model, closed-loop and SBAR-R29 communication, leadership and teamwork, and latent conditions.</p>		
	<p>Didactic only: Didactic training was based on the Team-STEPPS training curriculum, with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop communication, and shared mental model. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviors from the didactic training.</p>	Didactic training only	provider education

	Control : no intervention	Control (usual care)	usual care
Chaillet, 2015 ⁶	QUARISMA program: <i>Selection of opinion leader, audit committee and training</i> - The first 6 months of the 1.5-year intervention period focused on identifying the opinion leader in each intervention hospital (with the use of surveys) and selecting the local audit committee (which consisted of one or two obstetrician–gynecologists, one or two general practitioners, and one nurse), developing local expertise in conducting audits and providing feedback (1-day training), and improving the performance of health professionals in monitoring indications for cesarean delivery and managing intrapartum care (1-day training). <i>Audit and Feedback</i> - During the year after the training period, four 3-month audit cycles were implemented by audit committees, with the support of external facilitators who made quarterly educational outreach visits. Each cycle included five standardized steps: the identification of women who had cesarean deliveries during the first month of each cycle; the collection of data, with the use of standardized forms, regarding the management of labor and delivery; the assessment by the local audit committee, with the use of clinical algorithms, of the relevance of the indications for cesarean delivery; the formulation of recommendations for best practices and the evaluation of previous recommendations, both performed by the committee; and the provision of informal and formal feedback to health professionals. Control: No intervention from the QUARISMA team was planned for the control group. In order to assess contamination bias, quality-improvement programs were reviewed annually in control hospitals.	Multifaceted strategy (i.e. QUARISMA program) to promote professional onsite training	Provider education; Audit and feedback
Dumont, 2013 ⁷ [CR: Zongo, 2015 ⁸]	ALARM (Advances in Labour and Risk Management) international course for providers: 3 days of training in best practices in emergency obstetric care, 1 day of training in maternal death reviews, 1 day of awareness training related to economic, socio cultural, and ethical barriers (including sexual and reproductive rights), and 1 day of training in adult education methods. Two recertification sessions (once a year). <i>Multidisciplinary audit committee</i> including physicians, midwives, nurses, and administrators was created in each participating site and trained in the process of undertaking maternal death reviews. Control: hospitals randomised to the control group did not receive any intervention from the research team. Administrators of these hospitals were informed that the 6-day training workshop would be provided at the end of the trial	Multifaceted intervention (i.e. ALARM course) to promote maternity death reviews and onsite training	Provider education; Audit and feedback
Althabe, 2008 ⁹	Multifaceted behavioral intervention: <i>Selection of opinion leaders</i> - Teams of three to six birth attendants (physicians, residents, or midwives) were identified as opinion leaders by their peers at each intervention hospital with the use of a previously validated sociometric questionnaire. <i>Interactive workshops/training of manual skills</i> - Each team was trained in a 5-day workshop to develop and disseminate evidence-based guidelines on management of the third stage of labor and the use of episiotomy. The workshops focused on critical	Multifaceted behavioral intervention	Provider education; Clinician reminders

	<p>evaluation of the medical literature, development of clinical practice guidelines, communication skills, and methods of conducting one-on-one academic detailing visits with hospital birth attendants to discuss their views regarding implementation of the intervention at the hospital.</p> <p><i>Dissemination of training to hospital birth attendants, development of clinician reminders</i> - After returning to their respective hospitals, the teams participated in 1-day workshops to develop their training skills. The teams then disseminated the guidelines, trained and visited birth attendants, and developed reminders to be placed in labor and delivery wards, inside surgical packages for birth attendants, and on clinical records.</p> <p><i>Feedback</i> - The teams also produced monthly reports on rates of use of episiotomy and prophylactic oxytocin based on hospital clinical data. Regional coordinators met monthly with each team to assess completion of the activities.</p>		
	Control (seminar only): No intervention for the control group, but a seminar was held prior to baseline data collections to ensure all hospitals had similar knowledge at baseline	Control (standard in-service training)	provider education
Nielsen, 2007 ¹⁰	<p>MedTeams Labor & Delivery Team Coordination Course: teamwork training with principles based on crew resource management and a curriculum used in hospital emergency and obstetric departments. Crew resource management attempts to capitalize on the ability of each crew (team) member to see, analyze, and react to the same situation in ways that reduce the potential for error. Clinical staff from the seven intervention hospitals attended a 3-day instructor training session comprising 4 hours of didactic lessons, video scenarios, and interactive training covering team structure and processes, planning and problem solving, communication, workload management, team skills, and implementation. Conflict resolution strategies were included to provide a means of enhancing team behavior. Teamwork training also included assistance with creation and structure of teams at each intervention hospital. Trainers returned to their respective hospitals to conduct onsite training sessions for staff members from obstetrics, anesthesiology, and nursing and to structure each unit into core work teams made up of those nurses, physicians, and staff in direct contact with patients and coordinating teams composed of immediate supervisors, clinical leaders, and unit resource personnel. In addition, a contingency team, a multidisciplinary group of experienced physicians and nurses drawn from practitioners that are on call during a 24-hour period, were trained to respond in a coordinated way to obstetric emergencies.</p>	Teamwork training (i.e. MedTeams)	Provider education; Team change
	Control: no intervention for the control group	Control (usual care)	usual care
Horbar, 2004 ¹¹	<p>Multifaceted collaborative quality improvement intervention</p> <p><i>audit and feedback:</i> hospitals received confidential, individualised feedback from the Vermont Oxford Network including site-specific information and peer comparisons related to the administration and timing of surfactant, and delivery room practice for infants of 23-29 weeks' gestation born in 1998 and 1999;</p> <p><i>workshop:</i> included didactic sessions, facilitated site team exercises, and multi-institutional group exercises designed to promote four key "habits" (change, evidence</p>	Multifaceted collaborative intervention to promote evidence-based surfactant treatment	audit and feedback; provider education; team change

	based practice, systems thinking, and collaborative learning); <i>ongoing support:</i> Collaboration among intervention arm teams was fostered through quarterly conference calls and an email discussion list		
	Control (usual care with centre-specific routine reports): control hospitals received centre-specific, confidential reports routinely prepared for members of the Vermont Oxford Network.	Control (usual care with centre-specific routine reports)	audit and feedback
Colbourn, 2013 ¹²	Community mobilization and QI at health centres (FI+CI) <i>Community mobilization intervention:</i> 729 participatory women's groups to mobilize communities around maternal and newborn health, using 81 volunteer facilitators, supported by nine staff, across the allocated clusters and followed an "action cycle" (to identify and prioritize maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies) <i>Quality improvement intervention at health centres:</i> consisted of breakthrough series collaborative; coaching of facility staff in quality improvement methodology, such as developing change ideas, conducting small tests of change using Plan-Do-Study-Act cycles, to improve care at health centres; implementing change packages; conducting death reviews; and specific additional training, for local improvement leaders, and in situ training on specific clinical areas, such as neonatal resuscitation drills, and use of protocols for prevention and management of postpartum haemorrhage, sepsis and eclampsia.	Community mobilization intervention and facility-based QI intervention	Provider education; audit and feedback; patient education; continuous qi
	Quality improvement intervention at health centres (FI): consisted of breakthrough series collaborative; coaching of facility staff in quality improvement methodology, such as developing change ideas, conducting small tests of change using Plan-Do-Study-Act cycles, to improve care at health centres; implementing change packages; conducting death reviews; and specific additional training, for local improvement leaders, and in situ training on specific clinical areas, such as neonatal resuscitation drills, and use of protocols for prevention and management of postpartum haemorrhage, sepsis and eclampsia	Facility-based QI intervention only	Provider education; audit and feedback; continuous qi
	Community mobilization intervention (CI): 729 participatory women's groups to mobilize communities around maternal and newborn health, using 81 volunteer facilitators, supported by nine staff, across the allocated clusters and followed an "action cycle" (to identify and prioritize maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies)	Community mobilization intervention only	patient education
	Control: no community or facilities intervention	Control	usual care

Lumley, 2006 ¹³	<p>Pre-pregnancy health intervention: Women randomised to receive the intervention received a pre-pregnancy health intervention that consisted of:</p> <ol style="list-style-type: none"> 1. Identification of any current social, health or lifestyle problems. 2. Discussion of timing, planning and preparation for the next pregnancy 3. Offers of referral for any specific problem identified (e.g. to a dietician, relaxation group, physiotherapist, family planning clinic, general practitioner) all available at the Community Health Centre or nearby, or at a local hospital clinic; linkage with appropriate community resources (e.g. language-specific play-group) and networks. 4. Taking a family/genetic history and arranging a referral if necessary. 5. Arranging for rubella immunisation if not immune 6. Discussion of the points summarised on a WAIT, STOP, and GO reminder card. The card was headed Signs to follow before pregnancy, and designed to mimic traffic lights. The card included the name and address of the PPIS and the telephone number. 	Pre-pregnancy health intervention	team change; patient education; patient reminders
	<p>Control: All women recruited received a home visit from the PPIS midwife with a discussion of their first pregnancy, labour and birth and the postpartum experience. Any questions asked by the women were answered.</p>	Control	usual care
Olds, 2014 ¹⁴	<p>Transportation only: Women in treatment 1 were provided free transportation for prenatal care appointments.</p>	Transportation only	usual care
	<p>Transportation with screening and referral services: Women in treatment 2 were provided the transportation for prenatal care and developmental screening and referral services for their children at ages 6, 12, and 24 months.</p>	Transportation with screening and referral services	usual care

	<p>Transportation and home visits: Women in treatment 3 were provided the free transportation and nurse home visits during pregnancy plus 2 postpartum visits. Women in treatments 3 and 4 received a mean of 7 prenatal visits, and those in treatment 4 received a mean of 26 visits after delivery. The program guidelines include specific activities to support women’s protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.</p>	Transportation and home visits	case management; team change
	<p>Transportation and home visits with screening and referral services: Women in treatment 4 were provided the same services as those in treatment 3, plus home visits through child age 2 years as well as developmental screening and referrals for their children. Women in treatments 3 and 4 received a mean of 7 prenatal visits, and those in treatment 4 received a mean of 26 visits after delivery. The program guidelines include specific activities to support women’s protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.</p>	Transportation with screening and referral services, plus home visits	case management; team change
QI, quality improvement			

Appendix F – Outcome definitions by trial

Perinatal mortality

Althabe 2004 ⁴	Classified as perinatal mortality by author, no definition provided
Colbourn ¹²	Death of newborn within first 7 days of life
Lumley ¹³	Classified as perinatal mortality by author, no definition provided

Neonatal mortality

Althabe 2004 ⁴	Classified as neonatal mortality by author, no definition provided
Althabe 2008 ⁹	Classified as neonatal mortality by author, no definition provided
Colbourn ¹²	Death of newborn within first 28 days of life
Dumont ⁷	Death of newborn after the first day of life

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PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	6-8
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	7, Supplementary File 1; Appendix A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	7-8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	8-9
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary File 1; Appendix C

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	9
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	9-10
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	9-10, Supplementary File 1; Appendix B
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	10-12
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	10

Page 1 of 2

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	10-12
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	11, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	11, Supplementary File 1; Appendix D,E,F
Risk of bias within	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see	11-20

studies		item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	12-20, Table 1
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figure 2
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	21-22
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	22-23
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	24
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	25

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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BMJ Open

Patient safety initiatives in obstetrics: A Rapid Review

Journal:	<i>BMJ Open</i>
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Keywords:	OBSTETRICS, patient safety, quality improvement, review, knowledge synthesis, medical malpractice

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Patient safety initiatives in obstetrics: A Rapid Review

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27 ABSTRACT

28 **Objectives:** This review was commissioned by the World Health Organization (WHO), South
29 Africa – Country office because of an exponential increase in medical litigation claims related to
30 patient safety in obstetrical care in the country. A rapid review was conducted to examine the
31 effectiveness of quality improvement (QI) strategies on maternal and newborn patient safety
32 outcomes, risk of litigation, and burden of associated costs.

33 **Design:** A rapid review of the literature was conducted to provide decision-makers with timely
34 evidence. Medical and legal databases (e.g. MEDLINE, EMBASE, LexisNexis Academic, etc.)
35 and reference lists of relevant studies were searched. Two reviewers independently performed
36 study selection, abstracted data, and appraised risk of bias. Results were summarised narratively.

37 **Interventions:** We included randomised clinical trials (RCTs) of QI strategies targeting health
38 systems (e.g. team changes) and healthcare providers (e.g. clinician education) to improve the
39 safety of women and their newborns. Eligible studies were limited to trials published in English
40 between 2004 and 2015.

41 **Primary and secondary outcome measures:** RCTs reporting on patient safety outcomes (e.g.
42 stillbirths, mortality, and caesarean sections), litigation claims, and associated costs were
43 included.

44 **Results:** The search yielded 4,793 citations, of which 10 RCTs met our eligibility criteria and
45 provided information on over 500,000 participants. The results are presented by QI strategy,
46 which varied from one study to another. Studies including provider education alone (1 RCT),
47 provider education in combination with audit and feedback (2 RCTs) or clinician reminders (1
48 RCT), as well as provider education with patient education and audit and feedback (1 RCT),

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reported some improvements to patient safety outcomes. None of the studies reported on litigation claims or the associated costs.

Conclusions: Our results suggest that provider education and other QI strategy combinations targeting healthcare providers may improve the safety of women and their newborns during childbirth.

Keywords: Obstetrics, patient safety, quality improvement, review, knowledge synthesis, medical malpractice

Word Count: Abstract 297 (max 300), main text 4338 (suggested max 4000), 2 figures, 1 table, 2 supplementary files.

Strengths and limitations of this study

- A rapid review was conducted to identify quality improvement (QI) strategies for obstetrical care with supporting evidence from randomised clinical trials (RCTs) published in English between 2004 and 2015; a key limitation of the current review is the streamlined search and inclusion criteria used to accommodate the 6-week timeline for our decision-makers.
- To ensure the relevance of our review, commissioners from the WHO South Africa-Country office were engaged in defining the review scope, developing review questions, approving the protocol and literature search strategies, and identifying key messages.
- A comprehensive search of the medical and legal databases, websites, and reference lists of relevant studies were performed within the review scope.
- Study selection, data abstraction and quality appraisal were performed in duplicate to minimise subjectivity and random errors.

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INTRODUCTION

The rising costs in healthcare delivery and safety concerns of patients due to medical errors and liability claims have resulted in the development of policies to promote patient safety in medical practice.¹⁻⁴ An increase in the number of medical litigation cases and related costs is especially apparent in the field of obstetrics.⁵⁻⁷ Clinicians and decision-makers working in obstetrical care recognise the need to ensure the safety of patients, and many professional organisations (e.g. American College of Obstetricians and Gynecologists, National Health Service) have taken steps to make this a priority by evaluating current practices and introducing patient safety initiatives in their organisations.^{3 5 8} Implementation of patient safety initiatives, including quality improvement (QI) strategies, aim to reduce the occurrence of avoidable adverse events and improve the quality of care.^{8 9} QI strategies can target health systems (e.g. team changes, case-management), healthcare providers (e.g. provider education, audit and feedback), and/or patients (e.g. patient education, self-management). These strategies are typically complex interventions with interacting components involving various stakeholders and targeting more than one level of care.^{10 11} The evaluation of the effectiveness of these complex interventions is challenging and as such, the impact of QI interventions on patient safety outcomes remains unclear.

A scoping review on medical liability reforms and QI strategies to improve litigation-related outcomes in obstetrics identified several case studies with favourable findings.¹² Since these findings were primarily limited to case studies with small sample sizes, an examination of their effectiveness was not feasible. The current rapid review, therefore, aimed to examine the effectiveness of QI strategies on patient safety outcomes, medical litigation claims, and the associated costs.

93 METHODS

94 Commissioning Agency

95 Due to an exponential increase in litigation claims related to patient safety in obstetrical care in
96 South Africa, the World Health Organization (WHO) South Africa – Country Office
97 commissioned a review of patient safety initiatives. In order to provide decision-makers with
98 timely results, a rapid review approach was collectively agreed upon with a 6-week timeline for
99 completion. Rapid reviews tailor the systematic review process to produce information that is
100 relevant to decision-maker needs in an abbreviated period of time.¹³ The streamlined steps
101 followed in this review included limiting: the study design to randomised clinical trials (RCTs),
102 search dates to a period of 10 years, and language of publication to English.

103 Protocol

104 A protocol for this review was developed in collaboration with the review commissioner and
105 revised by the team systematic review methodologist (ACT) and clinician (SES) (Supplementary
106 File 1; Appendix A). The conduct and reporting of this review followed guidance from the
107 Preferred Reporting Items for Systematic Reviews and Meta-analysis (PRISMA) statement
108 (Supplementary File 2).¹⁴

109 Eligibility criteria

110 The following PICOST eligibility criteria were developed *a priori*:

111 **Population:** Pregnant women and/or newborns receiving care from professional healthcare
112 practitioners (e.g. physician, nurse, midwife) were eligible for inclusion.

113 **Interventions:** Interventions with the goal of promoting or ensuring patient safety in obstetric
114 care (full definitions are provided in Supplementary File 1; Appendix B) were eligible for

inclusion. The patient safety interventions (hereafter referred to as QI strategies) targeted health systems (e.g. clinician reminders, team changes) and/or healthcare providers (e.g. provider education, audit and feedback). Studies with interventions that only targeted patients (e.g. patient education, self-management) or community health workers (e.g. village leaders, volunteers) were excluded because the WHO was interested in interventions that they could implement at the health system or healthcare provider levels.

Comparators: Other patient safety interventions or usual care were eligible comparators.

Outcomes: Adverse safety outcomes (e.g. physical or mental damage or injury to the pregnant woman, fetus, or newborn), litigation claims (e.g. lawsuits or other legal action), and the associated costs (e.g. cost of patient safety initiatives to reduce harms and litigation or expenditure due to medical adverse event or legal outcome) were eligible for inclusion. The following outcomes were selected by the clinician (SES) on the team and review commissioner as key safety outcomes of interest: stillbirths, perinatal mortality, neonatal morality, maternal mortality, and caesarean sections. However, other patient safety outcomes (e.g. neonatal morbidity, blood loss, haemorrhage) reported in the included studies were also reported.

Study Design: Due to the rapid nature of the review, only RCTs, including cluster-randomised trials, were included. Quasi-randomised trials and non-randomised studies were not eligible for inclusion.

Other: Additional limits to accommodate the 6-week timeline included publication date (i.e. 2004-2015) and language of publication (i.e. English only).

Information sources and literature search

An electronic search of the literature was conducted in MEDLINE, EMBASE, LexisNexis Academic, LegalTrac and the Legal Scholarship Network on August 13, 2015. The search was

138 limited to RCTs (using a validated search filter),¹⁵ as well as papers published in English from
139 2004 to 2015.

140 The MEDLINE search strategy was developed by an experienced librarian (Dr. McGowan) in
141 consultation with the research team, approved by the review commissioner, and peer-reviewed
142 by another librarian (Dr. Cogo) using the Peer Review of Electronic Search Strategies (PRESS)
143 checklist.¹⁶ The final search strategy for MEDLINE can be found in Supplementary File 1;
144 Appendix C, and was adapted for the other electronic databases. The bibliographic search was
145 supplemented by searching websites of the WHO (<http://www.who.int/en/>) and Canadian
146 Medical Protective Association (<https://www.cmpa-acpm.ca/en/home>) and scanning reference
147 lists of all included RCTs.

148 **Study selection**

149 The search results were screened using our proprietary web-based tool, Synthesi.SR.¹⁷ The
150 inclusion criteria and screening questionnaires were established *a priori* for screening of titles
151 and abstracts, and full-text articles. To ensure inter-rater agreement, a random sample of 50
152 citations was pilot-tested among the review team with 100% agreement across reviewers. The
153 remaining search results were independently screened by pairs of reviewers (JA, WZ, VN, RC,
154 JDI, MG, CW, MK, RW, SM) and discrepancies were resolved by a third reviewer (JA, WZ).
155 The same process was followed for screening of potentially relevant full-text articles in which a
156 pilot-test was conducted on a random sample of 20 full-text articles with 90% agreement across
157 reviewers.

158 **Data abstraction**

159 Data were collected for predefined sets of items using a standardised form in Excel. Data items
160 included study characteristics (e.g. author, country of conduct, study design), patient

characteristics (e.g. target population, sample size), description of the QI strategies (e.g. provider education, team changes), and patient safety outcome results (e.g. stillbirths, neonatal mortality, litigation cases, costs). The form was pilot-tested on one article with a facilitated discussion to clarify discrepant items. Pairs of reviewers then abstracted data from each article, independently (JA, WZ, VN, RC, JDI, MG). Differences in abstraction were resolved by discussion and/or the involvement of a third team member (JA, WZ, VN, RC). The QI strategies used in each treatment arm were identified and categorised by an experienced systematic review methodologist (ACT) and clinician (SES) independently, and discrepancies were resolved through discussion.

Risk of bias assessment

Risk of bias of the included RCTs was assessed using the 7-item Cochrane Risk-of-Bias tool¹⁸ by pairs of reviewers independently (JA, WZ, VN, RC, JDI, MG). Since all reviewers were experienced with this tool, we did not conduct a pilot-test. For the “other bias” component of the tool, we assessed the potential for funding bias, as well as the presence of an imbalance in baseline numbers, risk of contamination, and confounding bias due to differences in treatment administration as described by the authors of the included studies. Discrepancies were resolved by a third reviewer (JA, WZ).

Synthesis

Study, patient, and intervention characteristics were summarised using descriptive analysis. All patient outcomes were synthesised narratively.

Patient involvement

182 No patients were involved in setting the research question or the outcome measures, nor were
183 they involved in the design and implementation of the study.

184 RESULTS

185 The literature search resulted in 4,793 citations (Figure 1). After screening for eligibility based
186 on titles and abstracts, 276 potentially relevant full-text articles were identified and screened for
187 inclusion. Ten RCTs¹⁹⁻²⁸ with one companion report²⁹ met the inclusion criteria and were
188 included.

189 Study characteristics

190 Although all RCTs were published from 2004-2015, they were conducted between the years of
191 1982 and 2011 with study durations ranging from 2^{19 24 26} to 21 years²⁷ (Supplementary File 1;
192 Appendix D). Over 500,000 participants were included across the RCTs from North America
193 (n=5),^{21 24 26-28} South America (n=2),^{19 20} Africa (n=2),^{22 23} and Australia (n=1).²⁵ Two RCTs
194 were randomised at the patient level (RCTs),^{25 27} while 8 were cluster-RCTs randomised at the
195 obstetrics unit, hospital, or district level.^{19-24 26 28}

196 Patient characteristics

197 Two RCTs described QI strategies targeting the health system, such as team changes and case
198 management. One of these RCTs focused on QI strategies implemented for the improvement of
199 outcomes in pregnant women alone,²⁵ while the other involved the care of pregnant women and
200 children up to 2 years of age (Supplementary File 1; Appendix D).²⁷ All cluster-RCTs described
201 QI strategies targeting healthcare providers, such as clinicians, nurses, and midwives.^{19-24 26 28}
202 The intervention settings of the RCTs were hospitals (n=8; 80%), and/or communities (n=3;
203 30%).

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Risk of bias appraisal

All 10 RCTs were assessed as having a low risk of ascertainment bias since the outcomes were examined using objective measures (e.g. blood loss; Figure 2). Seven RCTs (70%) were assessed as having a low risk of bias for random sequence generation, as well as low risk of attrition bias. About half of the RCTs were considered to be either high or unclear risk of bias for allocation concealment and selective reporting. Three studies were assessed as having a high risk of “other bias”^{21 25 28} due to systemic between-group differences in the distribution of baseline characteristics, potential bias due to uneven implementation of the intervention in different clusters, and/or failing to assess or adjust for other confounders (e.g. baseline risk of adverse pregnancy outcomes).

Patient safety outcomes

All RCTs reported on patient safety outcomes for mothers and their babies. In total, we identified 26 safety outcomes reported in the 10 studies. None of the 10 RCTs reported on outcomes related to litigation or associated costs. As each of the intervention components varied significantly, we were unable to statistically combine the results in a meaningful way using meta-analyses. Therefore, results were synthesized and summarised narratively. The findings of each study are presented below by intervention components. As a supplement to our results, detailed descriptions of each of the included interventions (Supplementary File 1; Appendix E), definitions of key outcomes (Supplementary File 1; Appendix F), and study-specific conclusions by outcome (Table 1) are also presented.

226 **Table 1. Summary Results of All Patient Safety Outcomes**

QI strategies	PE		PE+AF		PE+CLR	PE+TC	PE+AF+TC	PE+AF+PTE+CQI	PTR+TC+PTE	CM+TC
Study	Althabe, 2004 ¹⁹	Riley, 2011 ²⁸	Chaillet, 2015 ²¹	Dumont, 2013 ²³	Althabe, 2008 ²⁰	Nielsen, 2007 ²⁶	Horbar, 2004 ²⁴	Colbourn, 2013 ²²	Lumley, 2006 ²⁵	Olds, 2014 ²⁷
Sample Size	n = 149,276 women	n = 1,769 births/year	n = 184,952 women	n = 191,167 women	n = 5,466 deliveries	n = 28,536 deliveries	n = 6,039 newborns	n = 20,576 births	n = 786 women	n = 1,138 women
Risk of Bias	AC - Low, SB - Unclear	AC - Unclear, SB - Unclear	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - High, SB - Unclear	AC - Low, SB - Unclear	AC - High, SB - Unclear	AC - Low, SB - Unclear
Key Outcomes										
Stillbirths	0	-	-	0	0	-	-	0	-	?
Perinatal mortality*	0	-	-	-	-	-	-	✓	?	-
Neonatal mortality†	0	-	-	✓	0	-	-	✓	-	-
Maternal mortality	?	-	0	✓	?	-	-	0	-	?
Caesarean section‡	✓	-	✓	0	-	-	-	-	-	-
Other Outcomes										
Major neonatal morbidity	-	-	✓	-	-	-	-	-	-	-
Minor neonatal morbidity	-	-	✓	-	-	-	-	-	-	-
Infant pneumothorax	-	-	-	-	-	-	0	-	-	-
Unplanned admission to NICU	0	-	-	-	-	?	-	-	-	-
Infant/child deaths	-	-	-	-	-	-	0	-	-	?
1-min Apgar score < 3	-	-	-	-	-	-	0	-	-	-
5-min Apgar score < 4	-	-	0	-	0	-	-	-	-	-
5-min Apgar score 4-7	-	-	0	-	-	-	-	-	-	-
Major maternal morbidity	-	-	0	-	-	-	-	-	-	-
Minor maternal morbidity	-	-	0	-	-	-	-	-	-	-
Maternal admission to ICU	0	-	0	-	?	-	-	-	-	-
Systematic uterine rupture	-	-	0	-	-	-	-	-	-	-

QI strategies	PE		PE+AF		PE+CLR	PE+TC	PE+AF+T C	PE+AF+P TE+CQI	PTR+TC +PTE	CM+TC
Study	Althabe, 2004 ¹⁹	Riley, 2011 ²⁸	Chaillet, 2015 ²¹	Dumont, 2013 ²³	Althabe, 2008 ²⁰	Nielsen, 2007 ²⁶	Horbar, 2004 ²⁴	Colbourn, 2013 ²²	Lumley, 2006 ²⁵	Olds, 2014 ²⁷
Sample Size	n = 149,276 women	n = 1,769 births/year	n = 184,952 women	n = 191,167 women	n = 5,466 deliveries	n = 28,536 deliveries	n = 6,039 newborns	n = 20,576 births	n = 786 women	n = 1,138 women
Risk of Bias	AC - Low, SB - Unclear	AC - Unclear, SB - Unclear	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - Unclear, SB - Low	AC - Low, SB - Low	AC - High, SB - Unclear	AC - Low, SB - Unclear	AC - High, SB - Unclear	AC - Low, SB - Unclear
Perineal lacerations	-	-	o	-	o	?	-	-	-	-
Postpartum blood loss (mL)	-	-	-	-	✓	-	-	-	-	-
Postpartum haemorrhage > 500mL	-	-	-	-	✓	-	-	-	-	-
Postpartum haemorrhage > 1000mL	-	-	-	-	✓	-	-	-	-	-
Surfactant use (in delivery room)	-	-	-	-	-	-	✓	-	-	-
Surfactant use (2 hours post-delivery)	-	-	-	-	-	-	✓	-	-	-
Weighted adverse outcome score (WAOS) §	-	✓	-	-	-	o	-	-	-	-
Adverse outcome index (AOI)	-	-	-	-	-	o	-	-	-	-
Severity index	-	-	-	-	-	o	-	-	-	-
Legend: ✓, significantly protective; o, no difference; -, outcome not reported; ?, effect not reported										
Abbreviations: AC - allocation concealment; AF - audit and feedback; CLR - clinician reminders; CM - case management; CQI - continuous quality improvement; ICU - intensive care unit; NICU - neonatal intensive care unit; PE - provider education; PTE - patient education; PTR - patient reminders; QI - quality improvements; SB - selection bias; TC - team changes										

Footnotes:

*Colbourn, 2013 found community intervention was significantly protective when compared to no community intervention. All other comparisons in this study showed no significant difference.

† Dumont, 2013 found safety initiative to be statistically protective only <24hours after birth. Colbourn, 2013 found facility-based + community intervention to be significantly protective when compared to community intervention alone.

‡ Refers to non-Emergency C-sections

§ Of the three comparison arms, Riley 2011 only found the combination of didactic and in-situ training to be significantly protective. Didactic alone or in-situ alone showed no significant difference.

238 *Provider Education (n=2)*

239 Althabe *et al*¹⁹ compared the use of a mandatory second opinion by a clinician trained to use a
240 new decision-aid tool to usual care before caesarean section. This decision-aid tool provided
241 clinicians with suggestions and recommendations on how to prevent non-emergency caesarean
242 sections. This cluster-RCT of 149,276 pregnant women found a small significant reduction in the
243 rate of caesarean section for the intervention versus usual care (relative rate reduction 7.3%, 95%
244 CI 0.2-14.5). Other safety outcomes of maternal, perinatal and neonatal mortality, as well as
245 unplanned admission to the neonatal intensive care (NICU) and intensive care unit (ICU) showed
246 no significant differences between groups. This RCT had an unclear risk of selective reporting
247 bias and other bias.

248
249 The impact of team and staff training was evaluated in a cluster-RCT published by Riley and
250 colleagues²⁸. Three hospitals in the United States were compared in this RCT: one control
251 hospital (no intervention), one hospital used didactic training only (based on an evidence-based
252 teaching plan with a focus on leadership, situation monitoring, mutual support and
253 communication), and one hospital received the full intervention (didactic training with patient
254 simulations from triage through labour and recovery). The 4-year follow-up showed no
255 statistically significant differences in the pre- and post-intervention results in the hospitals
256 administering the control and didactic programs on the Weighted Adverse Outcome Score
257 (WAOS) including 10 adverse outcomes. However, the hospital receiving the full intervention
258 reported a statistically significant change in WAOS score, suggesting that a complex intervention
259 including didactic training with situational simulation can improve the safety of obstetrical

patients. This RCT had an unclear risk of bias on random sequence generation, incomplete outcome reporting, selective reporting bias, and allocation concealment.

Provider Education with Audit and Feedback (n=2)

A cluster-RCT by Chaillet *et al*²¹ conducted across 32 hospitals in Quebec assessed the effect of a multifaceted strategy to promote professional onsite training (including staff education, educational outreach, as well as audit and feedback) on the number of caesarean deliveries and other maternal and neonatal outcomes. No intervention was administered to the 16 hospitals in the control arm. During the 2 year intervention and follow-up period, there were 184,952 deliveries included. A small, statistically significant reduction in number of caesarean births were observed in the intervention arm (p=0.04). The intervention group also had statistically significantly lower major neonatal morbidity (p=0.03) and a significantly smaller increase in minor neonatal morbidity (p<0.001) when compared to the control group. There were no significant differences between groups in maternal morbidity. This RCT had a low risk of bias across all components except allocation concealment (unclear) and other risk of bias (high).

Dumont *et al*²³ reported the effects of a complex intervention in a cluster-RCT conducted in Senegal and Mali. The intervention arm included an initial interactive workshop on evidence-based clinical practice and the clinical audit process attended by opinion leaders (physicians and midwives) from 23 hospitals. The trained opinion leaders then returned to their respective hospitals to launch maternal death audits and provide on-site training, including quarterly educational outreach visits. The control arm included 95,236 patients in 23 hospitals that did not receive any intervention. Outcomes assessed at baseline and after 4 years of follow-up on a total of 191,167 patients found that maternal death reviews and on-site training may be beneficial for

certain populations. Compared to the control group, the intervention arm resulted in better maternal mortality rates (odds ratio 0.85, 95% CI 0.73-0.98), although this was limited to capital and district hospitals (where mild complications were managed as the first level of care, prior to the involvement of regional or national level hospitals). This RCT was assessed as having a low risk of bias on all components except random sequence generation and allocation concealment, which were both scored as having an unclear risk of bias.

Provider Education with Clinician Reminders (n=1)

Althabe *et al*²⁰ published a cluster-RCT exploring a multi-component behavioral intervention to facilitate the implementation of two evidence-based practices: the selective use of episiotomy and active management of the third stage of labour. The intervention involved the use of opinion leaders, staff training, and staff reminders. Ten hospitals in Argentina and Uruguay reporting 2,963 deliveries acted as the treatment arm. Nine hospitals with 2,503 vaginal deliveries formed the control group and received no intervention besides the standard in-service training. The outcomes of interest were assessed at baseline and at 18 months. When looking specifically at the adverse events to patients, there was a statistically significant relative rate reduction in postpartum haemorrhage and blood loss in the intervention arm at 500ml or more (45%, 95% CI 9 to 71) and 1000ml or more (70%, 95% CI 16 to 78). Maternal death, maternal admission to the intensive care unit, neonatal death, stillbirths, or Apgar score<4 did not result in a significant difference. The RCT was assessed as having an unclear risk of bias associated with random sequence generation and allocation concealment.

Provider Education with Team Changes (n=1)

Nielsen and colleagues²⁶ evaluated the effect of staff teamwork training on adverse outcomes in labour and delivery units in the United States. Teamwork training was administered in two parts

1
2
3 306 with selected staff attending training sessions on communication and team structure, and then
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5 307 returning to their home hospitals to train other staff members. Analysis was conducted on 28,536
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7 308 deliveries. The Adverse Outcome Index (AOI) was used to calculate the proportion of patients
8
9 309 with one or more adverse outcomes. The WAOS was also used to consider the relative severity
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11 310 of the included adverse outcomes. Some of the adverse events considered in these scores
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13 311 included maternal death, neonatal death, uterine rupture, maternal admission to the ICU,
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15 312 unplanned admission to the NICU, Apgar score <7, and birth trauma. However, no statistically
16
17 313 significant differences between groups were observed for the AOI, WAOS, or any of the
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19 314 individual adverse outcomes assessed. The risk of bias for this RCT was deemed low for all
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23 315 items except other risk of bias, which was unclear.

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27 316 *Provider Education with Audit and Feedback and Team Changes (n=1)*
28
29 317 The RCT by Horbar *et al*²⁴ evaluated a multi-component patient safety intervention to promote
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31 318 evidence-based surfactant treatment for preterm infants, including individualised audit and
32
33 319 feedback cycles, education and training of staff, and collaboration among intervention arm
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35 320 teams. Fifty seven hospitals administered the patient safety intervention, while another 57
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37 321 hospitals acted as the control. The use of surfactant in the delivery room was significantly higher
38
39 322 in the intervention group than the control group (adjusted odds ratio 5.38, 95% CI 2.84 to 10.20),
40
41 323 while the intervention hospitals had significantly lower surfactant treatment more than 2 hours
42
43 324 after birth when compared to the control hospitals (adjusted odds ratio 0.35, 95% CI 0.24 to
44
45 325 0.53). The other outcomes, including pneumothorax and infant mortality, were not found to be
46
47 326 significantly different. The RCT had a high risk of bias with respect to allocation concealment
48
49 327 and an unclear risk of selective outcome reporting bias.

328 *Provider Education with Audit and Feedback, Patient Education and Continuous Quality*

329 *Improvement (n=1)*

330 In rural Malawi, Colbourn *et al*²² conducted a two-by-two factorial cluster-RCT examining the
331 use of a women's group community intervention and a facility-based quality improvement
332 intervention to reduce maternal, perinatal and neonatal mortality. The first group received the
333 community intervention consisting of patient education, the second group received facility-based
334 provider education and audit and feedback, the third group received both community and
335 facility-based interventions, and the final group acted as a control arm. The analysis consisted of
336 5,080 in the community group, 5,335 in the facility group, 5,249 in the combined group, and
337 4,912 infant births in the control group. The community intervention group alone had a
338 significantly lower perinatal mortality rate (16% lower) when compared to control (adjusted odds
339 ratio 0.84, 95% CI 0.72 to 0.97). On the other hand, the neonatal mortality rate was 22% lower in
340 the facility-based + community interventions combined compared to control (adjusted odds ratio
341 0.78, 95% CI 0.60 to 1.01). No significant effects were reported for maternal mortality. The RCT
342 was assessed as having a low risk of bias on all items except selective outcome reporting, which
343 was unclear.

344 *Patient Reminders with Team Changes and Patient Education (n=1)*

345 Lumley *et al*²⁵ conducted a RCT in Australia to assess the impact of a pre-pregnancy
346 advice/counseling service offered to new mothers (initiated by two obstetricians) on the well-
347 being of their second-born children. There were 392 women in the intervention arm who were
348 identified after the birth of their first child. These women worked with a midwife (i.e. team
349 changes) to identify current health and lifestyle problems, assess family/genetic history, receive
350 education and referrals as needed, and discuss and develop an appropriate plan for their next

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3 351 pregnancy (including a reminder card). Meanwhile, 394 women in the control arm received a
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5 352 home visit with an opportunity to discuss their first pregnancy and ask questions. Outcomes were
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8 353 assessed after the birth of the second child. Infants born to mothers who received counseling
9
10 354 were more likely to be of lower birth weight than those who did not, and there were no
11
12 355 significant differences between the groups in secondary outcomes such as perinatal deaths and
13
14 356 congenital malformations. The RCT had an unclear risk of selective reporting bias, and high risk
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17 357 of bias on the allocation concealment, incomplete outcome data, and other bias items.
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20 358 *Case Management and Team Changes (n=1)*
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22 359 One RCT was conducted to determine the effect of prenatal and infant home visits by nurses on
23
24 360 maternal and child mortality by Olds *et al*²⁷. Participants, mostly African-American women
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27 361 residing in very poor neighborhoods, were randomised to one of four treatment arms during
28
29 362 pregnancy and were followed for 2 years. In treatment 1, 166 women received free transportation
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31 363 for prenatal appointments. In addition to transport, 514 women in treatment 2 also received some
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33 364 developmental screening and referral services. The third treatment arm including 230 women
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36 365 added nurse home visits during pregnancy as well as 2 postpartum home visits, while 228
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38 366 women in treatment 4 received the most comprehensive intervention with transport, screenings,
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41 367 nurse home visits during pregnancy and until the child was 2 years old. Maternal and infant
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43 368 mortality outcomes were collected for all treatment arms after two years of follow-up.
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45 369 Participants in the combined control arm (treatment 1 + treatment 2) had more natural,
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48 370 preventable, and total infant deaths when compared to women receiving a combined intervention
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50 371 including treatment 3 and 4. Survival curves were created for each of the treatment arms. When
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52 372 projecting to 21 years after randomisation, all-cause mortality in mothers was statistically
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55 373 significantly higher in treatment 1 + treatment 2 when compared to treatment 3 alone (p=0.007)
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or when compared to treatment 3 + treatment 4 (P=0.008). The RCT was assessed as having an unclear risk of allocation concealment, incomplete outcome data and selective reporting bias.

DISCUSSION

We conducted a rapid review and identified 10 RCTs written in English and published between 2004 and 2015 on complex interventions that can be used to improve patient safety in obstetrics. The included RCTs examined a broad range of complex patient safety interventions in obstetrics with some treatment arms including only one QI strategy, while others were multi-faceted interventions including up to four QI strategies. Many of the included studies had a provider education component and the results suggest that this intervention, when combined with other QI strategies, may improve outcomes. Results from two RCTs indicated that provider education with audit and feedback may improve patient safety, specifically by lowering neonatal morbidity and caesarean births,²¹ as well as neonatal and maternal mortality,²³ when compared to usual care. In another RCT, patient's receiving provider education combined with clinician reminders had reduced postpartum blood loss and haemorrhage when compared to control groups in similar settings.²⁰ Finally, an RCT comparing the use of provider education with patient education and audit and feedback compared to community intervention alone, demonstrated an improvement in patient safety through a reduction in neonatal mortality.²² A future comprehensive systematic review that considers quasi-experimental and observational study designs should be conducted on this topic to provide a definitive conclusion on whether these interventions are indeed effective. Such a systematic review may be able to include more studies, allowing the conduct of a meta-analysis of the QI strategies versus usual care and potentially quantifying the effectiveness of these interventions.

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3 397 The quality of the included RCTs was generally high, with a few areas of concern. It was unclear
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5 398 whether randomisation sequence was sufficiently concealed, or whether selective outcome
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7 399 reporting was present, since these items were unclear for half of the included studies. Also, 6 out
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10 400 of 10 RCTs were graded as either ‘unclear’ or ‘high risk of bias’ for the “other bias” category, as
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12 401 differences in baseline characteristics or confounding effects due to differences in treatment
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14 402 administration across providers, departments, or hospitals were concerns reported by the study
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16 403 authors themselves.
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21 405 A major strength of our review was the timely provision of high-quality evidence for decision-
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23 406 makers. Our rapid review methodology included a comprehensive search of the literature using
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25 407 multiple databases, and study selection, data abstraction and risk of bias assessment performed in
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27 408 duplicate by pairs of reviewers. However, as with any rapid review, there are also some
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29 409 limitations to be considered. We had to methodologically tailor our review to suit the decision-
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31 410 makers needs by limiting results to RCTs published in English within a 10 year time frame. In
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33 411 addition, the literature search was conducted in August 2015 for the purpose of submitting a
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35 412 report to the review commissioners who did not request that we update our findings. Moreover,
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37 413 variation in administration and implementation of the QI strategies across settings is
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39 414 unavoidable, especially in cluster-RCTs, where each hospital acts as an independent unit.
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41 415 Consideration should be made of possible confounding effects as a result of the hospital setting
42
43 416 and care practices (e.g. duration, frequency, and provider). Given the number and range of
44
45 417 patient safety initiatives included in each study, it is difficult to ascertain how each of the
46
47 418 components included in the multi-faceted, complex interventions directly contributed to the
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49 419 observed effects. Additionally, it was challenging to compare across studies as the QI strategies
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420 were used to address different clinical questions in each (e.g. prenatal home visits by midwives
421 to reduce preterm births compared to teamwork training in hospitals to promote guideline
422 implementation). The differences in these complex interventions meant we were unable to
423 conduct meta-analysis. Moreover, classifying complex interventions, such as QI strategies, is
424 challenging³⁰ and required two individuals with complementary expertise to conduct this task.
425
426 Finally, we did not identify any randomised controlled trials specifically addressing litigation
427 claims or undue costs to the healthcare system. However, evidence from non-randomised studies
428 suggests that there may be a relationship between a reduction in adverse safety outcomes and a
429 reduction in litigation and losses due to medical errors and malpractice. These reports^{5 31} have
430 found that the introduction of patient safety programs, involving a combination of strategies
431 targeting health systems and healthcare providers, have resulted in the reduction of not only
432 obstetrical adverse events, but also the number of litigation claims and resulting costs. In
433 addition, the community and facility-based interventions evaluated in the Colbourn *et al*²² trial
434 were shown to be highly cost-effective in an economic evaluation conducted by the study
435 authors.³² Further research is needed to examine the effectiveness and cost-effectiveness of
436 patient safety interventions for adverse events, litigation claims and associated costs.

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CONCLUSIONS

Our results suggest that provider education and other QI strategy combinations targeting healthcare providers may improve the safety of women and their newborns during childbirth. In addition, improved patient safety may influence the risk of medical litigation claims and associated costs, however no direct evidence was found for these outcomes. A future systematic review, including a meta-analysis, may be able to provide more definitive conclusions.

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List of Abbreviations

AC: allocation concealment; AF: audit and feedback; AOI: adverse outcome index; CI: confidence interval; CLR: clinician reminders; CM: case management; C-section: caesarean section; CQI: continuous quality improvement; ICU: intensive care unit; NICU: neonatal intensive care unit; PE: provider education; PRESS: peer review of electronic search strategies; PRISMA: preferred reporting items for systematic reviews and meta-analyses; PTE: patient education; QI: quality improvement; RCTs: randomised clinical trials; TC: team changes; WAOS: weighted adverse outcome score; WHO: World Health Organization

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Provenance and peer review

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Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

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Author’s Contribution

JA coordinated the review, screened citations and full-text articles, abstracted data, appraised risk of bias, cleaned the data, interpreted the results, and wrote the manuscript. WZ co-coordinated the review, screened citations and full-text articles, abstracted data, appraised risk of bias, cleaned the data, and edited the manuscript. BP helped conceptualize the research, interpreted the results, and edited the manuscript. VN, RC, JDI, and MG screened citations and full-text articles, abstracted data, appraised risk of bias, and edited the manuscript. SLB helped conceive the study and edited the manuscript. SES conceived the study, designed the study, obtained the funding, interpreted the results, and edited the manuscript. ACT conceived the study, designed the study, obtained the funding, interpreted the results, and wrote some of the manuscript. All authors approved the final version to be published.

Competing interests

All authors declare that they have no competing interests.

Figures

Figure 1. Study Flow Diagram. Breakdown of the number of studies identified in the literature, assessed for eligibility, and finally included in the rapid review on patient safety initiatives in obstetrics.

Figure 2. Risk of Bias. Aggregate Cochrane Risk-of-Bias appraisal results

For peer review only

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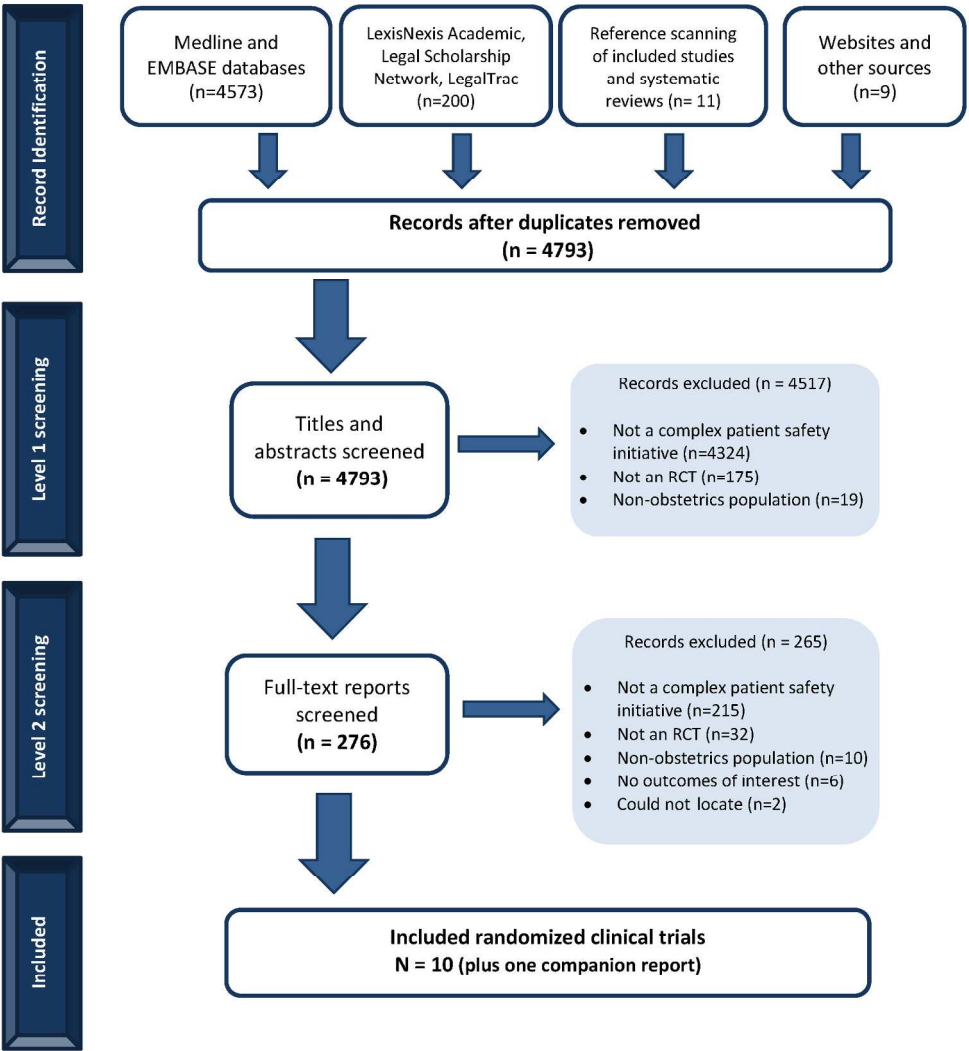
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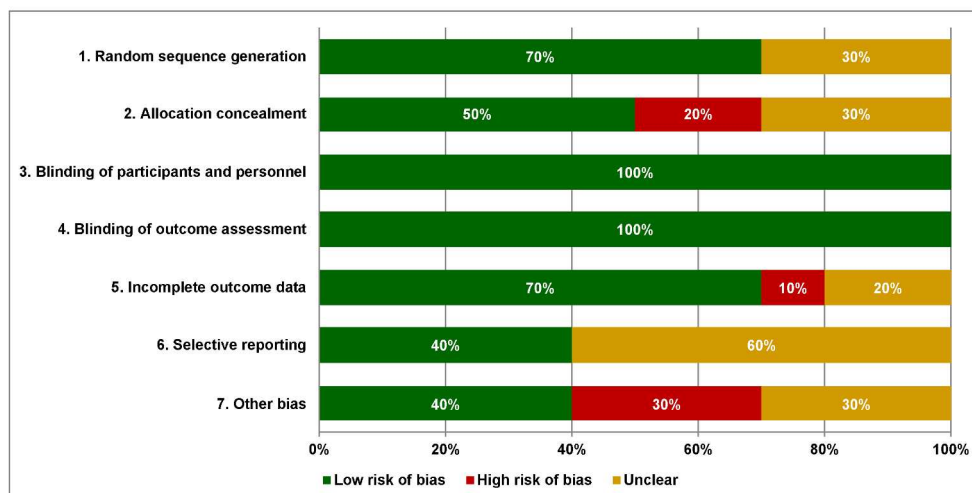
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Study Flow Diagram. Breakdown of the number of studies identified in the literature, assessed for eligibility, and finally included in the rapid review on patient safety initiatives in obstetrics.

190x207mm (300 x 300 DPI)



Risk of Bias. Aggregate Cochrane Risk-of-Bias appraisal results

238x121mm (300 x 300 DPI)

Patient safety initiatives in obstetrics: A Rapid Review
Appendices

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Appendix A – Protocol

METHODS:

To answer the research question “What are the available randomised clinical trials that evaluate patient safety interventions in obstetrical care?” we propose doing a rapid scoping review. Below is our proposed method for this rapid scoping review.

Scoping reviews

A scoping review aims to “map the literature on a particular topic or research area and provide an opportunity to identify key concepts, gaps in the research; and types and sources of evidence to inform practice, policymaking, and research”.¹ A scoping review essentially follows the same steps of a systematic review recommended by the Cochrane Collaboration,² except the quality of included studies is not appraised because the purpose is to map out the literature and identify areas to conduct future systematic reviews.

Rapid reviews

Rapid reviews are a form of knowledge synthesis in which components of the systematic review process are simplified or omitted to produce information in a timely manner.³ Depending on the scope and timelines, rapid reviews will streamline some of the processes recommended by the Cochrane Collaboration, such as only 1 reviewer screening the literature search results, abstracting data, and appraising quality. A meta-analysis generally is not conducted for a rapid review.

We have conducted rapid scoping reviews for the World Health Organization (in 2011) and Toronto-Central-Local Health Integrated Network (in 2012) and the lead scientist (Dr. Tricco) on this proposal is interested in studying and improving scoping review and rapid review methods.

Search Strategy

We will use the methodologically rigorous rapid scoping review approach. We will conduct a systematic search across the following electronic databases from inception onwards: MEDLINE (OVID interface), EMBASE (OVID interface), LexisNexis Academic, and the Legal Scholarship Network. The general search terms included those related to obstetrics and patient safety interventions. In order to limit the search, we focused on randomised clinical trials and publications in English from 2004 onwards.

A search conducted on August 13, 2015 of MEDLINE and EMBASE using the defined terms retrieved approximately 5000 citations. We aim to also search to legal databases after we further refine the search strategy with input from the investigators and in consultation with our experienced information specialist. The search strategy has already been peer reviewed by another librarian using the Peer Review of Electronic Search Strategies (PRESS) checklist (see PubMed ID: 19230612). After this exercise, the search strategy was finalised. The information specialist will execute all final searches, export the results into EndNote, and remove all

duplicates from the search results. The results will then be uploaded to Synthesi.SR (<http://knowledgetranslation.ca/sysrev/login.php>), proprietary software available through the Li Ka Shing Knowledge Institute of St. Michael's Hospital.

The following PICOS informed the search strategy:

- Patients:* all obstetrics patients
- Interventions:* patient safety initiatives
- Comparators:* compared to each other or no initiative
- Outcomes:* litigation (number of cases), costs, patient harm (specifically cerebral palsy, shoulder dystocia, non-reassuring fetal status, birth-related neurological injuries)
- Studies:* randomised clinical trials

Study Selection: Screening

Prior to commencing the screening process, a calibration exercise will be conducted to ensure reliability in correctly selecting articles for inclusion. This will entail screening a random sample of 5% of the included citations by all team members, independently. Eligibility criteria will be modified if low agreement is observed between the reviewers (e.g., percent agreement <90%). Two reviewers will then independently screen the remainder of the search results for inclusion using a pre-defined relevance criteria form for all levels of screening (e.g., title and abstract, full-text review). Discrepancies will be resolved by discussion or the involvement of a third reviewer.

Data Abstraction:

A data abstraction form will be drafted and pilot-tested by all team members independently on a random sample of 10 articles and revised iteratively by the study team while the search is completed. It is anticipated that the data items will include information related to the outcomes of interest. Pairs of team members will independently read each article and extract the relevant data. Differences in abstraction will be resolved by discussion or the involvement of a third reviewer.

Synthesis

We will narratively describe the included randomised clinical trials. If possible, a meta-analysis will be considered after the preliminary report has been submitted to Dr. Sarah Barber and her team of the World Health Organization. We will present the outcome results in tables and categorised by intervention, obstetrical issue, and country of origin.

Appendix B – Quality Improvement (QI) Strategies; Full Definitions

Complex Intervention

Complex interventions are important to resolve the common, complex challenges in health care. Quality improvement strategies are considered complex interventions. Complex interventions require detailed descriptions of the intervention to enable researchers to replicate the study, synthesise the results, and implement findings. However, details of complex interventions are often underreported in research. A falls prevention program for seniors is an example of a complex intervention because it often has more than one interacting component administered within the intervention group. For example, the intervention group may receive exercise training with a physiotherapist (exercise training), the physiotherapist may receive training to administer the program specifically to elderly patients (clinician education), and the patients may receive education about falling (patient education). These interventions are challenging to deliver or receive, target more than one level of organisation (e.g., both the patient and healthcare provider levels), include multiple dosages and formulations, and allow for the tailoring of interventions across settings (e.g., physiotherapist uses slightly different approaches for different patients in the intervention group).

QI strategies targeting health systems

Case management	Any system for coordinating diagnosis, treatment, or routine management of patients (e.g., arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician. If the study called the intervention “case management” we classified it as such.	Includes nurse phoning regularly to check on patient, nurse calling to promote diet adherence, discharge planning, post-hospital services and home visits
Team changes	Changes to the structure or organisation of the primary health-care team (adding team member, multidisciplinary teams, expansion or revision of professional roles)	Includes multidisciplinary collaboration, appointments with specialists, attending a obstetrics clinic, referrals to specialists or other healthcare providers
Electronic patient registry	General electronic medical record system or electronic tracking. Do not include websites unless patients were tracked over time. To qualify, it had to be a part of the clinical trial as an intervention (i.e., not pre-existing infrastructure unless used more actively)	
Facilitated relay of info to clinicians	Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record (excluding conventional means of correspondence between clinicians.)	
Continuous	Interventions explicitly identified as	

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QI	involving the techniques of continuous QI, total quality management, or plan-do-study-act, or any iterative process for assessing quality problems, developing solutions to those problems, testing their effects, and then reassessing the need for further action	
QI strategies targeting health-care providers		
Audit & feedback	Summary of clinical performance of health care delivered by an individual clinician or clinic over a specified period, which was then transmitted back to the clinician. This strategy was strictly based on clinical data and excluded clinical skills. It could include the number of patients with missing tests and dropouts.	
Provider education	Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target disorder or population of patients. Includes conferences or workshops, distribution of educational materials (written, video, or other), and educational outreach visits.	Includes staff training, education workshops, seminars, and outreach
Clinician reminders	Paper-based or electronic systems intended to prompt a health professional to recall patient-specific information (e.g., most recent HbA1c value) or to do a specific task (e.g., foot examination).	
Financial incentives	Interventions with positive or negative financial incentives directed at providers (eg, linked to adherence to some process of care or achievement of some target outcome). This strategy also includes positive or negative financial incentives directed at patients or system-wide changes in reimbursement	Includes gym memberships, drug assistance programs, free medications, Rides to the intervention or parking is not included
QI strategies targeting patients		
Promotion of self-management	Provision of equipment or access to resources to promote self-management. If the study called the intervention promotion of self-management, personalised goal-setting, or action-planning, we included it here. We generally thought this a more active strategy than education of patients)	Includes problem-solving skills, tracking the number of steps (fit bit), self-help groups

Patient Reminders	Any effort (e.g., postcards or telephone calls) to remind patients about upcoming appointments or important aspects of self-care. If the intervention included case management, reminders to patients needed to be explicit.	Includes reminder cards, emails, telephone calls
Patient education - written materials, videos, lectures, other	Patient education related to health	Includes pamphlets, booklets/sheets, brochures on safety initiatives, as well as videos, classes, lectures, workshops, other - "instructions" (unspecified) to promote safety
Motivational interviewing	Motivational interviewing ("a directive and client-centered counselling style that relies upon identifying and mobilising the client's intrinsic values and goals to stimulate behaviour change, thus encouraging client and family involvement in all aspects of care.")	Motivational interviewing

Appendix C – Medline Search strategy

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

1 Obstetrics/
2 "Obstetrics and Gynecology Department, Hospital"/
3 exp Obstetric Surgical Procedures/
4 obstetric\$.tw,hw.
5 exp Obstetric Labor Complications/
6 exp "Dilatation and Curettage"/
7 exp Hysterectomy/
8 Sterilization, Tubal/
9 Salpingostomy/
10 exp Pregnancy Complications/
11 cerebral palsy/
12 Asphyxia Neonatorum/
13 (abortion\$ or cervical cerclage or colpotomy or culdoscop\$ or fetoscop\$ or hysteroscop\$ or
14 hysterotomy).tw.
15 (paracervical block\$ or obstetric\$ anesthe\$ or obstetric\$ anaesthe\$).tw.
16 (Cesarean or Episiotom\$ or obstetric\$ extraction\$ or fetal version).tw.
17 ((induc\$ or augmentation or premature or pre-term or preterm or obstructed) adj (labour or
18 labor)).tw.
19 (Abruptio Placentae or breech or Cephalopelvic Disproportion or premature rupture of fetal
20 membrane\$ or prom or fetal membranes premature rupture or Dystocia or Uterine Inertia or
21 Chorioamnionitis or Placenta Accreta or Placenta Previa or Postpartum Hemorrhage or Uterine
22 Inversion or Uterine Rupture or Vasa Previa).tw.
23 (Fetal Death or Fetal Resorption or Stillbirth or perinatal death or peri-natal death or
24 Maternal Death or Birth Injuri\$ or obstetric\$ paralys\$).tw.
25 (pre-eclampsia or dilatation or Curettage or Vacuum aspiration).tw.
26 (asphyxia neonatorum or cerebral palsy or birth asphyxia or fetal pulmonary embolism or
27 dystocia or ((birth adj (trauma\$ or complication\$)) or preeclampsia) or ((birth adj (trauma\$ or
28 complication\$)) or preeclampsia)).tw.
29 exp Dystocia/ or exp Pregnancy Complications, Cardiovascular/
30 or/1-21
31 (safe\$.ti,ab. or exp Safety/ or Err\$.ti,ab. or Adverse.ti,ab.) and (exp Risk Management/ or
32 exp Quality of Health Care/ or exp Medical Errors/ or Safety Management/ or Medical Audit/)
33 patient safety/
34 (patient safe\$ or obstetric\$ safe\$).tw.
35 22 and (23 or 24 or 25)
36 case [reports.pt](#).
37 Observational [Study.pt](#).
38 (News or Newspaper Article or comment or editorial).pt.
39 or/27-29
40 randomized controlled [trial.pt](#).

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3 32 (randomized or placebo).mp.
4 33 clinical [trial.pt](#).
5 34 or/31-33
6 35 comparative [study.pt](#).
7 36 26 and 34
8 37 limit 36 to english
9 38 limit 37 to yr=2004-2015
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Appendix D – Patient and Intervention Characteristics

First Author, Year	Study Design	Study Period	Intervention Provider	Abbreviated Intervention Name	QI Strategy	Intervention Setting	Intervention Setting Description	Sample Size	Duration/ Frequency of intervention
Althabe, 2004 ⁴	cluster RCT	Oct 1998 - Jun 2000	physicians	Decision aid tool training and mandatory second opinion (educational seminar offered to all prior to randomisation)	Provider education	Hospital	18 hospitals (9 in Argentina, 4 in Brazil, 2 in Cuba, 1 in Guatemala, 2 in Mexico)	70,410 pregnant women who underwent delivery	6 months pre-intervention; 7 month intervention
				Control (educational seminar offered to all prior to randomisation)	Provider education	Hospital	18 hospitals (9 in Argentina, 4 in Brazil, 2 in Cuba, 1 in Guatemala, 2 in Mexico)	78,866 pregnant women who underwent delivery	6 months pre-intervention; 7 month intervention
Riley, 2011 ⁵	cluster RCT	2005 - 2008	labour and delivery staff	Didactic training with in-situ patient simulations	Provider education	Hospital	small-sized community hospitals (50 beds); rural/suburban in the US	36 medical personnel; 380 births/year	4 months (30 min webinar, 11 in-situ simulations (30-40mins), 2-hour debriefing immediately following each)
				Didactic training only	Provider education	Hospital	small-sized community hospitals (66 beds); rural/suburban in the US	60 medical personnel; 889 births/year	4 months (30min webinar)
				Control (usual care)	usual care	Hospital	small-sized community hospitals (55 beds); rural/suburban	38 staff; 500 births/year	4 months

							in the US		
Chaillet, 2015 ⁶	cluster RCT	Apr 2008 - Oct 2011	physicians and nurses	Multifaceted strategy (i.e. QUARISMA program) to promote professional onsite training	Provider education; Audit and feedback	Hospital	16 public hospitals in Quebec, Canada	84,227 pregnant women who underwent delivery	3.5 years (1 year pre-intervention, 1.5 intervention, 1 year post-intervention)
				Control (usual care)	usual care	Hospital	16 public hospitals in Quebec, Canada	100,725 pregnant women who underwent delivery	3.5 years (1 year pre-intervention, 1.5 intervention, 1 year post-intervention)
Dumont, 2013 ⁷ [CR: Zongo, 2015 ⁸]	cluster RCT	Sept 2007 - Oct 2011	obstetric teams	Multifaceted intervention (i.e. ALARM course) to promote maternity death reviews and onsite training	Provider education; Audit and feedback	Hospital	23 public first-level and second-level referral hospitals in Senegal and Mali	95,931 pregnant women who underwent delivery	1 year pre-interventions; 2 year intervention (initial 6-day training workshop for healthcare professionals and quarterly educational clinically oriented and evidence-based outreach visits); 1 year post-intervention

				Control (usual care)	usual care	Hospital	23 public first-level and second-level referral hospitals in Senegal and Mali	95,236 pregnant women who underwent delivery	1 year pre-interventions; 2 year intervention; 1 year post-intervention
Althabe, 2008 ⁹	cluster RCT	Sept 2003 - Dec 2006	birth attendants	Multifaceted behavioral intervention	Provider education; Clinician reminders	Hospital	public maternity hospitals (9 in Argentina and 1 in Uruguay)	baseline: 2,963 vaginal deliveries; post-intervention: 2,587 vaginal deliveries; 295 birth attendants	intervention: 18 months; post-intervention follow-up: 12 months
				Control (standard in-service training)	Provider education	Hospital	public maternity hospitals (8 in Argentina, 1 in Uruguay)	baseline: 2,503 vaginal deliveries; post-intervention: 2,366 vaginal deliveries; 237 birth attendants	intervention: 18 months; post-intervention follow-up: 12 months
Nielsen, 2007 ¹⁰	cluster RCT	Dec 2002 - Mar 2004	clinical staff	Teamwork training (i.e. MedTeams)	Provider education; Team change	Hospital	7 US hospitals (3 military and 4 civilian)	14,200 total deliveries; 1,307 trained personnel	2 month pre-intervention; 3-day training; 5 month post-intervention

				Control (usual care)	usual care	Hospital	8 US hospitals (3 military and 5 civilian)	14,336 total deliveries	2 month pre-intervention; 5 month post-intervention
Horbar, 2004 ¹¹	cluster RCT	May 1999 - Dec 2001	hospital staff	Multifaceted collaborative intervention to promote evidence-based surfactant treatment	Audit and feedback; provider education; team change	Hospital	57 neonatal intensive care units in hospitals in the Vermont Oxford Network, US	3,313 newborns	1 year (one time individualised feedback; 2-day workshop; routine reports)
				Control (usual care with centre-specific routine reports)	Audit and feedback	Hospital	57 neonatal intensive care units in hospitals in the Vermont Oxford Network, US	2,726 newborns	1 year (routine reports)
Colbourn, 2013 ¹²	cluster RCT	Jun 2007 - Dec 2010	volunteer facilitators, village women's groups, health centre facility staff	Community mobilisation intervention and facility-based QI intervention	Provider education; audit and feedback; patient education; continuous qi	Community and Hospital	14 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,249 births	16 months pre-intervention; 27 months intervention
			health centre facility staff	Facility-based QI intervention only	Provider education; audit and feedback; continuous qi	Hospital	15 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,335 births	16 months pre-intervention; 27 months intervention

			volunteer facilitators, village women's groups	Community mobilisation intervention only	patient education	Community	15 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	5,080 births	16 months pre- intervention; 27 months intervention
			NA	Control	usual care	Hospital	17 clusters (the catchment population of a health centre) in three districts of the central region of Malawi	4,912 births	16 months pre- intervention; 27 months intervention
Lumley, 2006 ¹³	RCT	May 1982 - Dec 1994	midwives	Pre-pregnancy health intervention	Team change; patient education; patient reminders	Community	Maternal and Child Health (MCH) centres, Australia	392 pregnant women who underwent delivery	one home visit for general pregnancy discussion and as needed during pregnancy
				Control (usual care)	usual care	Community	Maternal and Child Health (MCH) centres, Australia	394 pregnant women who underwent delivery	one home visit for general pregnancy discussion
Olds, 2014 ¹⁴	RCT	Jun 1990 - Dec 2011	community nurse	Transportation only	usual care	Community	public system of obstetric and pediatric care in Memphis, Tennessee,	166 pregnant women who underwent delivery	as needed during pregnancy

					US	
			Transportation with screening and referral services	usual care	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US
						514 pregnant women who underwent delivery
						as needed during pregnancy and once post-partum
			Transportation and home visits	case management; team change	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US
						230 pregnant women who underwent delivery
						as needed during pregnancy and two visits post-partum
			Transportation with screening and referral services, plus home visits	case management; team change	Community	public system of obstetric and pediatric care in Memphis, Tennessee, US
						228 pregnant women who underwent delivery
						as needed during pregnancy and until child 2 years of age
NA, not applicable; QI, quality improvement; RCT, randomized clinical trials; US, United States						

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Appendix E – Intervention descriptions

First Author, Year	Intervention Description	Abbreviated Intervention Name	QI Strategy
Althabe, 2004 ⁴	Seminar, Guidelines and Mandatory second opinion: The intervention consisted of the implementation of a policy of mandatory second opinion at the hospitals assigned to the intervention group. Second opinion was to be sought by the attending physician systematically before caesarean section. The physician providing the second opinion had to be a person with clinical qualifications equal to or higher than those of the attending physician, working at the same hospital, selected by the obstetrics department for this trial, and who had agreed to follow the clinical guidelines. A physician could have the role of attending physician on some days and consultant on others. To assess the clinical case, the consultant followed guidelines prepared as decision flowcharts, for six primary indications for caesarean section. Each guideline had suggestions about how to deal with the problem that originated the indication. Both physicians discussed the case in relation to the guidelines. After this process, the attending physician made the final decision. The guidelines were made available for all physicians at intervention hospitals. NOTE: All decisions to undertake caesarean sections (either elective or intrapartum) in intervention hospitals were eligible for a mandatory second opinion, except if the woman specifically refused to be seen by a second doctor or the situation was an extreme emergency such as maternal haemorrhage, cord prolapse, suspected uterine rupture, or any situation where the attending physician judged that a delay would constitute malpractice.	Decision aid tool training and mandatory second opinion (educational seminar offered to all prior to randomisation)	provider education
	Control (seminar only): a formal seminar on pregnancy and delivery care offered to all clinicians prior to randomisation	Control (educational seminar offered to all prior to randomisation)	provider education
Riley, 2011 ⁵	Didactic with in-situ simulation: <i>Didactic Training:</i> Didactic training was based on the Team-STEPPS training curriculum, with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop	Didactic training with in-situ patient simulations	provider education

	<p>communication, and shared mental model. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviours from the didactic training.</p> <p><i>In-Situ Simulation:</i> The in-situ simulation for perinatal critical events consisted of five components: (a) briefing, (b) in-situ simulation, (c) debriefing, (d) rapid-cycle follow-through with process improvements, and (e) repetition to reinforce skills and create resiliency. During the briefing, participants who were directly involved in the simulation were educated about the simulation scenarios. The simulated patient was followed from triage, through labor and the operating room (OR), and then to the recovery area. The simulation, which typically ran 30 to 45 minutes, was initiated in a manner similar to a typical handoff, with a brief history from one provider to the next. A two-hour debriefing session, with the use of advanced debriefing techniques, was held immediately following each simulation. Scenarios and triggers were taken from actual occurrences in the hospital unit. We used an event-set methodology to develop scenarios for uterine rupture, placental abruption, and post-partum haemorrhage. The event sets specified phases for each of the three scenarios. Five clinical triggers were designed to prompt NTS behaviors: situational awareness, shared mental model, closed-loop and SBAR-R29 communication, leadership and teamwork, and latent conditions.</p>		
	<p>Didactic only: Didactic training was based on the Team-STEPPS training curriculum, with a focus on four learnable, teachable skills to improve team performance: leadership, situation monitoring, mutual support, and communication. The TeamSTEPPS program is an extensive curriculum that involves several days of classroom training. We focused specifically on the following behaviors to develop a condensed curriculum for critical skills that are necessary for effective communication in safety-critical environments: situational awareness, standard communication of Situation-Background-Assessment-Recommendation-Readback (SBARR), closed-loop communication, and shared mental model. A 30-minute audiovisual webinar presentation of these four key TeamSTEPPS skills was developed for the participants. The participants completed a 10-item test at the conclusion of the didactic training, with a 90% score as a target to track learner comprehension. We created obstetrical emergency scenarios based on incidents abstracted from actual sentinel events for use in the in-situ simulation team training sessions. We used an event-set methodology in the simulation scenario that incorporated the same key TeamSTEPPS behaviors from the didactic training.</p>	Didactic training only	provider education
	Control : no intervention	Control (usual care)	usual care

Chaillet, 2015 ⁶	<p>QUARISMA program: <i>Selection of opinion leader, audit committee and training</i> - The first 6 months of the 1.5-year intervention period focused on identifying the opinion leader in each intervention hospital (with the use of surveys) and selecting the local audit committee (which consisted of one or two obstetrician–gynecologists, one or two general practitioners, and one nurse), developing local expertise in conducting audits and providing feedback (1-day training), and improving the performance of health professionals in monitoring indications for cesarean delivery and managing intrapartum care (1-day training). <i>Audit and Feedback</i> - During the year after the training period, four 3-month audit cycles were implemented by audit committees, with the support of external facilitators who made quarterly educational outreach visits. Each cycle included five standardised steps: the identification of women who had cesarean deliveries during the first month of each cycle; the collection of data, with the use of standardised forms, regarding the management of labor and delivery; the assessment by the local audit committee, with the use of clinical algorithms, of the relevance of the indications for cesarean delivery; the formulation of recommendations for best practices and the evaluation of previous recommendations, both performed by the committee; and the provision of informal and formal feedback to health professionals.</p>	Multifaceted strategy (i.e. QUARISMA program) to promote professional onsite training	Provider education; Audit and feedback
	<p>Control: No intervention from the QUARISMA team was planned for the control group. In order to assess contamination bias, quality-improvement programs were reviewed annually in control hospitals.</p>	Control (usual care)	usual care
Dumont, 2013 ⁷ [CR: Zongo, 2015 ⁸]	<p>ALARM (Advances in Labour and Risk Management) international course for providers: 3 days of training in best practices in emergency obstetric care, 1 day of training in maternal death reviews, 1 day of awareness training related to economic, socio cultural, and ethical barriers (including sexual and reproductive rights), and 1 day of training in adult education methods. Two recertification sessions (once a year). <i>Multidisciplinary audit committee</i> including physicians, midwives, nurses, and administrators was created in each participating site and trained in the process of undertaking maternal death reviews.</p>	Multifaceted intervention (i.e. ALARM course) to promote maternity death reviews and onsite training	Provider education; Audit and feedback
	<p>Control: hospitals randomised to the control group did not receive any intervention from the research team. Administrators of these hospitals were informed that the 6-day training workshop would be provided at the end of the trial</p>	Control (usual care)	usual care
Althabe, 2008 ⁹	<p>Multifaceted behavioral intervention: <i>Selection of opinion leaders</i> - Teams of three to six birth attendants (physicians, residents, or midwives) were identified as opinion leaders by their peers at each intervention hospital with the use of a previously validated sociometric questionnaire. <i>Interactive workshops/training of manual skills</i> - Each team was trained in a 5-day workshop to develop and disseminate evidence-based guidelines on management of the third stage of labor and the use of episiotomy. The workshops focused on critical evaluation of the medical literature, development of clinical practice guidelines,</p>	Multifaceted behavioral intervention	Provider education; Clinician reminders

	<p>communication skills, and methods of conducting one-on-one academic detailing visits with hospital birth attendants to discuss their views regarding implementation of the intervention at the hospital.</p> <p><i>Dissemination of training to hospital birth attendants, development of clinician reminders</i> - After returning to their respective hospitals, the teams participated in 1-day workshops to develop their training skills. The teams then disseminated the guidelines, trained and visited birth attendants, and developed reminders to be placed in labour and delivery wards, inside surgical packages for birth attendants, and on clinical records.</p> <p><i>Feedback</i> - The teams also produced monthly reports on rates of use of episiotomy and prophylactic oxytocin based on hospital clinical data. Regional coordinators met monthly with each team to assess completion of the activities.</p>		
	Control (seminar only): No intervention for the control group, but a seminar was held prior to baseline data collections to ensure all hospitals had similar knowledge at baseline	Control (standard in-service training)	provider education
Nielsen, 2007 ¹⁰	<p>MedTeams Labor & Delivery Team Coordination Course: teamwork training with principles based on crew resource management and a curriculum used in hospital emergency and obstetric departments. Crew resource management attempts to capitalise on the ability of each crew (team) member to see, analyze, and react to the same situation in ways that reduce the potential for error. Clinical staff from the seven intervention hospitals attended a 3-day instructor training session comprising 4 hours of didactic lessons, video scenarios, and interactive training covering team structure and processes, planning and problem solving, communication, workload management, team skills, and implementation. Conflict resolution strategies were included to provide a means of enhancing team behavior. Teamwork training also included assistance with creation and structure of teams at each intervention hospital. Trainers returned to their respective hospitals to conduct onsite training sessions for staff members from obstetrics, anesthesiology, and nursing and to structure each unit into core work teams made up of those nurses, physicians, and staff in direct contact with patients and coordinating teams composed of immediate supervisors, clinical leaders, and unit resource personnel. In addition, a contingency team, a multidisciplinary group of experienced physicians and nurses drawn from practitioners that are on call during a 24-hour period, were trained to respond in a coordinated way to obstetric emergencies.</p>	Teamwork training (i.e. MedTeams)	Provider education; Team change
	Control: no intervention for the control group	Control (usual care)	usual care
Horbar, 2004 ¹¹	<p>Multifaceted collaborative quality improvement intervention</p> <p><i>audit and feedback:</i> hospitals received confidential, individualised feedback from the Vermont Oxford Network including site-specific information and peer comparisons related to the administration and timing of surfactant, and delivery room practice for infants of 23-29 weeks' gestation born in 1998 and 1999;</p> <p><i>workshop:</i> included didactic sessions, facilitated site team exercises, and multi-institutional group exercises designed to promote four key "habits" (change, evidence based practice, systems thinking, and collaborative learning);</p>	Multifaceted collaborative intervention to promote evidence-based surfactant treatment	audit and feedback; provider education; team change

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	<i>ongoing support:</i> Collaboration among intervention arm teams was fostered through quarterly conference calls and an email discussion list		
	Control (usual care with centre-specific routine reports): control hospitals received centre-specific, confidential reports routinely prepared for members of the Vermont Oxford Network.	Control (usual care with centre-specific routine reports)	audit and feedback
Colbourn, 2013 ¹²	Community mobilization and QI at health centres (FI+CI) <i>Community mobilization intervention:</i> 729 participatory women's groups to mobilise communities around maternal and newborn health, using 81 volunteer facilitators, supported by nine staff, across the allocated clusters and followed an "action cycle" (to identify and prioritise maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies) <i>Quality improvement intervention at health centres:</i> consisted of breakthrough series collaborative; coaching of facility staff in quality improvement methodology, such as developing change ideas, conducting small tests of change using Plan-Do-Study-Act cycles, to improve care at health centres; implementing change packages; conducting death reviews; and specific additional training, for local improvement leaders, and in situ training on specific clinical areas, such as neonatal resuscitation drills, and use of protocols for prevention and management of postpartum haemorrhage, sepsis and eclampsia.	Community mobilisation intervention and facility-based QI intervention	Provider education; audit and feedback; patient education; continuous qi
	Quality improvement intervention at health centres (FI): consisted of breakthrough series collaborative; coaching of facility staff in quality improvement methodology, such as developing change ideas, conducting small tests of change using Plan-Do-Study-Act cycles, to improve care at health centres; implementing change packages; conducting death reviews; and specific additional training, for local improvement leaders, and in situ training on specific clinical areas, such as neonatal resuscitation drills, and use of protocols for prevention and management of postpartum haemorrhage, sepsis and eclampsia	Facility-based QI intervention only	Provider education; audit and feedback; continuous qi
	Community mobilization intervention (CI): 729 participatory women's groups to mobilize communities around maternal and newborn health, using 81 volunteer facilitators, supported by nine staff, across the allocated clusters and followed an "action cycle" (to identify and prioritise maternal and neonatal health problems, decide upon local solutions, advocate for, implement and evaluate such strategies)	Community mobilisation intervention only	patient education
	Control: no community or facilities intervention	Control	usual care

Lumley, 2006 ¹³	<p>Pre-pregnancy health intervention: Women randomised to receive the intervention received a pre-pregnancy health intervention that consisted of:</p> <ol style="list-style-type: none"> 1. Identification of any current social, health or lifestyle problems. 2. Discussion of timing, planning and preparation for the next pregnancy 3. Offers of referral for any specific problem identified (e.g. to a dietician, relaxation group, physiotherapist, family planning clinic, general practitioner) all available at the Community Health Centre or nearby, or at a local hospital clinic; linkage with appropriate community resources (e.g. language-specific play-group) and networks. 4. Taking a family/genetic history and arranging a referral if necessary. 5. Arranging for rubella immunisation if not immune 6. Discussion of the points summarised on a WAIT, STOP, and GO reminder card. The card was headed Signs to follow before pregnancy, and designed to mimic traffic lights. The card included the name and address of the PPIS and the telephone number. 	Pre-pregnancy health intervention	team change; patient education; patient reminders
	<p>Control: All women recruited received a home visit from the PPIS midwife with a discussion of their first pregnancy, labour and birth and the postpartum experience. Any questions asked by the women were answered.</p>	Control	usual care
Olds, 2014 ¹⁴	<p>Transportation only: Women in treatment 1 were provided free transportation for prenatal care appointments.</p>	Transportation only	usual care
	<p>Transportation with screening and referral services: Women in treatment 2 were provided the transportation for prenatal care and developmental screening and referral services for their children at ages 6, 12, and 24 months.</p>	Transportation with screening and referral services	usual care

	<p>Transportation and home visits: Women in treatment 3 were provided the free transportation and nurse home visits during pregnancy plus 2 postpartum visits. Women in treatments 3 and 4 received a mean of 7 prenatal visits, and those in treatment 4 received a mean of 26 visits after delivery. The program guidelines include specific activities to support women’s protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.</p>	Transportation and home visits	case management; team change
	<p>Transportation and home visits with screening and referral services: Women in treatment 4 were provided the same services as those in treatment 3, plus home visits through child age 2 years as well as developmental screening and referrals for their children. Women in treatments 3 and 4 received a mean of 7 prenatal visits, and those in treatment 4 received a mean of 26 visits after delivery. The program guidelines include specific activities to support women’s protection of their health including eating balanced diets; avoiding substance use, unsafe sexual practices, and risky social relationships; engaging in exercise and hygiene; and advocating for themselves with providers of office-based care. The program guidelines provide extensive support to caregivers in their efforts to care well for their children, including promoting safe sleep practices (e.g., placing babies on their backs during nap time and at night), ensuring safe sleep environments, reducing hazards in the home, and supporting regulated, responsive care of the child.</p>	Transportation with screening and referral services, plus home visits	case management; team change
QI, quality improvement			

Appendix F – Key outcome definitions by trial

Stillbirths [baby born with no signs of life at or 28 weeks of pregnancy]¹⁵

Althabe 2004 ⁴	Classified as stillbirths by author, no details provided
Althabe 2008 ⁹	Classified as stillbirths by author, no details provided
Colbourn ¹²	The ICD-10 criteria for stillbirth modified to include births after 28 weeks instead of 22 weeks of pregnancy
Dumont ⁷	Classified as stillbirths by author, no details provided
Olds ¹⁴	Classified as stillbirths by author, no details provided

Perinatal mortality [stillbirths with a gestational age of 28 weeks or more and deaths in the first week of life (early neonatal deaths)]^{16 17}

Althabe 2004 ⁴	Classified as perinatal mortality by author, no details provided
Colbourn ¹²	Death of newborn within first 7 days of life
Lumley ¹³	Classified as perinatal mortality by author, no details provided

Neonatal mortality [death of a newborn within the first four weeks of life]¹⁷

Althabe 2004 ⁴	Classified as neonatal mortality by author, no details provided
Althabe 2008 ⁹	Classified as neonatal mortality by author, no details provided
Colbourn ¹²	Death of newborn within first 28 days of life
Dumont ⁷	Death of newborn <24 hours after birth (early) or after the first day of life (late)

Maternal mortality [death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes]¹⁸

Althabe 2004 ⁴	Classified as maternal mortality by author, no details provided
Althabe 2008 ⁹	Classified as maternal death by author, no details provided
Colbourn ¹²	Death of a woman while pregnant or within 42 days of termination of pregnancy from any cause related to the pregnancy
Chaillet ⁶	Classified as maternal death by author, no details provided
Dumont ⁷	Classified as hospital-based maternal mortality, no details provided
Olds ¹⁴	Categorized into natural deaths or external deaths. Natural causes in this sample included neoplasms, human immunodeficiency virus infection, sickle cell anemia, diabetes mellitus, endocarditis, stroke, renal disease, acidosis, aortic dissection, and pulmonary embolism. External causes included drug overdose, suicide, unintentional injuries, and homicide.

Caesarean sections [surgical delivery of infants for medically indicated or elective reasons]¹⁹

Althabe 2004 ⁴	Elective/non-emergency or intrapartum caesarean section
Chaillet ⁶	Classified as caesarean delivery, no details provided
Dumont ⁷	Elective/non-emergency caesarean sections

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PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	2-3
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	5
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	5-7
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	6, Supplementary File 1; Appendix A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	6-7
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	7-8
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Supplementary File 1; Appendix C

Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	8
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8-9
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	8-9, Supplementary File 1; Appendix B
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	9
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	NA
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	9

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Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	9
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	NA
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	10, Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	10, Supplementary File 1; Appendix D,E,F
Risk of bias within	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see	10-20

studies		item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	11-20, Table 1
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	NA
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Figure 2
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	NA
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	20-21
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	21-22
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	23
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	24

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